NATIONAL NANOTECHNOLOGY COORDINATION OFFICE

on behalf of

NANOSCALE SCIENCE, ENGINEERING, AND

TECHNOLOGY (NSET) SUBCOMMITTEE,

COMMITTEE ON TECHNOLOGY

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NATIONAL SCIENCE AND TECHNOLOGY COUNCIL (NSTC)

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Public Meeting on Research Needs Related to the

Environmental, Health, and Safety Aspects of

Engineered Nanoscale Materials

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Thursday

January 4, 2007

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The public meeting was convened at the Federal Deposit Insurance Corporation, 3501 North Fairfax Drive, Arlington, Virginia, at 9:00 a.m.

CONVENING PANEL:

DR. NORRIS ALDERSON	FDA, NSET's Working Group on Nanotechnology Environmental and Health Implications, Chair
CLAYTON TEAGUE	National Nanotechnology Coordination Office Director
CELIA MERZBACHER	NSET Subcommittee, Co-Chair, Office of Science and Technology Policy
ALTAF CARIM	NSET Subcommittee, Co-Chair, Dept. of Energy, Office of Basic Energy Sciences

DR. DIANNE POSTER	NIST, Dept. of Commerce
DR. SALLY TINKLE	NIEHS, NIH
DR. PHIL SAYRE	EPA
DR. VLADIMIR MURASHOV	NIOSH
DR RICHARD CANADY	FDA

PRE-REGISTERED PRESENTATIONS:

MR. PETER LINQUITI
DR. ERIC LANDREE
MR. PAUL ZIEGLER
DR. VLADIMIR MURASHOV
DR. ANDREW MAYNARD
DR. BETTYE MADDUX
DR. RAMA VENKATASUBRAMANIAN
MR. SEAN MURDOCK
DR. DAVID BERUBE
DR. JO ANNE SHATKIN
MR. GEORGE KIMBRELL
DR. JIM WILLIS

C O N T E N T S

P R O C E E D I N G S

(9:01 a.m.)

DR. ALDERSON: Good morning, for the members of the Nanoscale Science, Engineering, and Technology Subcommittee and also the Nanotechnology Environmental Health Implications Working Group, we welcome you to this meeting.

We appreciate your interest in this subject and your willingness to work with the NEHI members to provide input on this important subject of environmental health and safety research as related to nanotechnology.

For those of you that do not know me, I'm Norris Alderson, and I'm chair of the Nanotechnology Environmental and Health Implications Working Group, and this is a working group of the NSET Subcommittee, which is a subcommittee of the Council on Technology.

Let me take care of a few administrative and logistics issues for everyone. The restrooms are out the back door to our right and back down the hall. In fact, they're right on the other side of this door here.

The staff at FDIC here has asked that if you have Blackberries, please shut those off because they have found that there is feedback in the sound

system from the blackberries. I also ask that you put your cell phones on vibrate.

There are lounge areas outside the back doors or on either side. So if you need to go take a phone call, you need to have some private conversations, I think those areas will be great for that.

I really want to thank the National Nanotechnology Coordinating Office for all of their work for making the arrangements for this meeting. Cate, Audrey Haar, and Victor have done a great job of getting us all here, and I hope this will be a successful day in that respect.

The FDIC staff has also been very helpful.

We ask that the speakers come down and sit in these front two rows. That way we'll facilitate getting you on and off the stage without a loss of time.

We ask that the NSET and the NEHI members sit in the first two rows in this section so that will facilitate the questioning sessions.

Back on December 8th, 2006, the National Nanotechnology Coordinating Office published a notice of a meeting to be held today on the subject of environmental health and safety research.

Specifically, NEHI and NSET are asking for the public input on two specific issues as related to EHS.

One is we need input from you, the public, on the research areas that we published in the document that was released on September, I believe, 16th. That's the part we're engaged in now in NEHI. That's the prioritization of those research areas.

Those areas are what we asked for, and it's the subject of this meeting. So we genuinely want your thoughts on those research areas and how we should prioritize those. Which should come first? Which are the most important areas that we need to work on with the available dollars?

I want to point out that this meeting is part of a process, and I'll talk more about that later, of how we not only establish those research priorities, but how do we keep evaluating where we are to insure that we are effectively utilizing the dollars available, to facilitate bringing this technology to the consumer.

A few thoughts as background on NEHI and issues that we need to frame the subject for today. NEHI is a multi-agency working group of the NSET Subcommittee. We meet monthly, almost every month, since it was formed. Primarily there are 30

participants involved, representing 24 different agencies.

The members of NEHI are both from research and regulatory agencies, and the purposes of NEHI were very prominent up front when NEHI was formed, and that's really to establish early recognition of what it is in terms of environmental health and safety needs for this new technology.

It was formed in August 2003, and when it was formed, as well as myself and Dr. Andrew Maynard, who has subsequently left and gone to the Woodrow Wilson Center, he and I were co-chairs at that time. But Andrew was involved very prominently up front.

Further, in framing the issues of environmental health and safety research is the funding that's already going on in this arena. There has been research funded through the NNI process since 2001, and that has gradually increased. What we project now in 2007 is $44 million.

Now, it's important to keep in mind that the categorization of that research in those areas in the past was based on a definition that was in the supplemental document as related to the funding. Using that definition, it did not include research on environmental interactions of nanoengineered materials

with biosystems. It did not include research to develop new instrumentation, metrology or measuring exposure to and for characterizing engineered .

In the current document that was published in September, we established five research areas as needs for addressing the environmental health and safety issues associated with nanotechnology.

Where we are today is through OMB and the budget process, we are requesting, using the new definition in the document in the five research areas, that the funding agencies provide us their 2006 information based on that categorization rather than the old definition.

So I think we all agree in NEHI at least that when we get the new information, which will be coming soon from the funded agencies, we will have a better fix on where we are with what's been funded. And we'll talk a little bit more about that in a few minutes as it relates to a gap analysis.

If you probably read and are keeping up with what everyone is saying about the need for environmental health and safety research, some will say there is an over estimate of these numbers on this slide or over estimate of what we've spent. Others will say we're not spending enough.

But I think with the process that we're currently working on, we will have a fix on what we are spending based on the needs that we've identified.

The importance of the research is to insure that when we introduce a new nanomaterial into the marketplace, we have a good fix on what are the risks of that particular material. We need to identify and characterize the potential hazards such that we know what the risks are associated with a given route of exposure.

We need to develop methods to make nanomaterials benign to the environment, biological systems, and human health, and we need to have methods that risk managers can use to realize the benefits of nanotechnology.

The first step of the process that we're involved in today at this meeting really started when NEHI and NNCO, NSET released the document last September, and in this document there are two definitions, I think, that are paramount that we all have as a background of how we're going to define what we're talking about today.

The first is engineered nanoscale materials, and short, nanomaterials. But it is important to understand in that definition we're

talking about both manufacturing material for a specific purpose and, secondly, it has a scaled dimension.

It's funny. In the scaled dimension, you see this rarely. It's one to 100 nanometers, but I know at least at FDA we frequently see materials that are different as a result of the scale size, not necessarily within that one to 100 range. So I think it depends a lot on where you are and what you're working with every day, but at least we recognize that there is a dimension part of this definition of nanomaterial.

The second one is the environmental health and safety or EHS. Within NEHI, before the document was filed, we had many discussions on this definition. If you've ever looked at this very much, if you go to Google and just search on EHS, you get a full range of potential definitions depending on where you are and how you want to use it.

So in view of the representation on NEHI, particularly in the regulatory agencies, we define this, as you see it here, but it's environmental health, human health, animal health and safety. And those are the issues which we're defining the research agenda or research portfolio that's needed to address

these particular areas as related to nanomaterials.

So what did the document really do in terms of identifying the areas? And as I said earlier, there are five specific areas in the document. If you don't have one, I hope you'll pick one up some time during today because they're out on the table for you, but it identified research and information needs. It is a cumulative input of all the agencies, both research and regulatory that are represented on NEHI.

But it also represented input from both the industry and the international arena because there have been a lot of publications already on this subject.

But in the final analysis, after putting everything on the table, we were able to group the research needs into the five categories, and they're reflected in the document, and that's one of the things we asked for input on at this meeting. What does the public think about those five areas and also the individual research components in each?

We see these research areas being used to guide program and funding decisions by federal agencies. Certainly the information that comes from this will be used by the regulatory agencies.

We also believe that it would be of value to the industry, universities, and other non-government research organizations.

So the other area we wanted your input on is on the prioritization process. If you have got the document in front of you, I believe on page 9, are our thoughts at the time on how we would prioritize these particular research components. That's part of the process we're currently in.

But we had a number of areas there. One was the, quote, value of the information. Under that value of information there are a number of areas. First was to reduce the uncertainty of risk. I think for all of us, identification of the key uncertainties as related to the nanomaterial is extremely important.

Secondly, broad knowledge. It's better to take a look at the properties and behavior of classes of nanomaterials rather than a single nanomaterial that has a very narrow use.

So how can we apply principles to identify uncertainty in very broad classes? What's going to be the use of the nanomaterial? Is it going to have a very broad application, many uses, or is it going to be a single use material? Again, what's the best way or best utilization of the dollars available?

What's the exposure potential? I think all of us have been talking about this now since NEHI was formed. Our first priority is exposure to the workers, the unintentional exposure of workers, consumers, and the environment.

For the intentional exposure, such as in the things that FDA will deal with, our process will take care of those environmental, health and safety materials, but unintentional exposure, we need to be able to address that.

And finally, we need to leverage the existing data that are available, particularly as it relates to incidental materials like diesel fumes, for instance. We have a lot of information already available in that arena. So how can we use that to guide us in defining environmental health and safety issues associated with these now engineered nanomaterials?

The second area of our look at how we should prioritize is how do we leverage international in the private sector. We need to maximize this, and this is perhaps one of the most difficult areas, particularly when you're talking about the international arena, and how do you work with those international organizations to assure that working

together you get the best utilization of the available dollars?

I've listed here a few of the organizations just as examples of the things that representatives of NEHI and NSET already work in: International Council on Nanotechnology, ICON; the Consultative Boards on Advancing Nanotechnology, CBAN; Organization of Economic Cooperation and Development. Jim Willis here is a leader in that arena as it relates to OECD representing the U.S. government. We have a lot of activity going on there.

In our standards setting arena, ASTM, IEEE, and others. We're working with those to develop standards and nomenclature. International Organization for Standardization, SAME, and we have ongoing activities both as NEHI, but individually our representative agencies also meet with their counterparts on these issues, particularly in the European Community.

I know we were very aligned and have regular conversations with the European Union at FDA, and I know this is going on with the other agencies as well.

So there's a lot of opportunity there, but not an easy one to work with them.

Our third component of principles of prioritizations, the adaptive management, and this is a difficult one, too. Nanotechnology as a technology is advancing very fast. So the challenge then becomes how do you keep up in the EHS arena as that technology is advancing, and we must do that. Very difficult.

The bottom line, we've got to be very efficient with the research dollars and make sure we do things that are smart. We don't duplicate research across the agencies or even across the international community, but it's very challenging.

And the fourth arena is what we're doing today, having regular opportunities for the public to provide us input into this process, and it's an ongoing process, not only from an oral presentation. We are here today, but providing us written comments.

So what's the process? And that's where we are on this slide when we talk about next steps. Within NSET, since the document published in September, NEHI has been working within those five areas to come up with ways and means to prioritize those specific areas.

And if you'll look in the document, there are about 75 specific research areas within those five categories. So we've been looking at ways to work to

prioritize those and, again, we need your input on that process.

I mentioned earlier that we're going to be getting through OMB and the budget process a new look at what the agencies have currently funded in 2006 using the five categories that are in the document.

We are holding a public meeting as we are today, and once we get your input on how we should prioritize and what the priorities should be, and looking at what the agencies tell us they're currently --

(Pause in proceedings for teleconference operator interruption.)

DR. ALDERSON: We knew this was going to be a problem, but we'll proceed.

But once we have that information from what you're going to give us today and the information from the funded agencies, we'll look at where were the gaps, and that will be our final document. And once we look at those gaps, what the priorities are based on how we should prioritize. Hopefully you're going to give us your thought on how to do that today.

Following that then becomes in some respects -- the very difficult part is how do we coordinate that with the funded agencies, recognizing

that NSET and NEHI have no authority over any of the funded agencies and how they spend their dollars. Hopefully internally we can twist some arms to at least start addressing those key areas that we need to address, and we'll talk some more about that shortly.

And the last, we're going to have to find a way to regularly update the priorities. How often should there be a relook? Should the priorities or means of prioritization change?

And I think there are many ways to redo that on a scheduled basis, but it's going to take time and effort on a lot of people's part to make this continue to happen. And I'm sure Clayton and others will make sure that is the way we work.

But the bottom line is we want this to be a very dynamic, open, and transparent process. So I think you'll be hearing more about meetings like this where we will specifically request your input.

In the announcement, we also provided for the opportunity to provide written comments. So there is a Web site that you can submit written comments to, and we encourage you to do that if you choose not to speak today or for those who could not come today. That is an opportunity we hope everyone will take advantage of.

Okay. Let's move to today's agenda. Working within NEHI, we've established five I guess I can call them committees, if you will, that are working within NEHI to deal with the five research areas, and those five individuals are sitting here, and you're going to hear from each of them shortly. But these are very key individuals in the five areas:

Dr. Dianne Poster from the National Institute of Standards and Technology, on instrumentation, metrology and analytical methods;

Dr. Sally Tinkle from the National Institute of Environmental Health and Safety, nanomaterials and human health;

Dr. Phil Sayre from EPA, nanomaterials and environment;

Dr. Vladimir Murashov from the National Institute of Occupational Health and Safety, on health and environmental surveillance;

And Dr. Richard Canady from FDA on the risk management methods.

They're going to give you a framework, if you will, of the five areas and what's within those five areas so they can set the stage for what we're going to hear from each of the outside speakers on.

Following their presentations, we will

move into the public presentations. For those that met the pre-deadline date of registration, they will have 15 minutes for their presentation, and that will be followed by ten minutes of questions from the NEHI members.

And the reason for this is we want the NEHI members to be the recipient and understand what the speaker is telling us about specific areas and prioritization, as well as the particular research areas. These folks are the ones that are going to have to deal with it in the coming months.

We've also provided the opportunity for those who did not meet the pre-deadline registration date to speak to register since then, and you can even register today if you so like, and you will be given five minutes at the end of the day to speak.

So if after you've heard some things this morning you decide you would like to speak, there's an opportunity for you at the end of the day.

One thing that I forgot to do early on was introduce the three people to my left, and I apologize to them for that oversight, but they are very key in what's going on in nanotechnology.

Dr. Clayton Teague is Director of the National Nanotechnology Coordinating Office.

Dr. Celia Merzbacher is from the Office of Science and Technology Policy.

And Dr. Altaf Carim, from the Department of Energy.

Celia and Altaf are co-chairs of NSET, very key leadership positions in the national nanotechnology initiative, and you'll hear from one of them later. I don't know which yet.

So with that, we will start our presentations from the outside speakers. A few rules regarding the speakers.

One, you need to come up from either end, not here. We don't want anybody falling and having to call an ambulance to take you to the hospital because this is a dangerous area here.

Secondly, for the outside speakers, you're going to have a light here for you. Fifteen minutes it goes to red, I think, and so you'll know if you should be winding up at that time and then we'll have ten minutes for speakers.

We are on a very tight schedule, if you've looked at the agenda. So we will try to stay on schedule as much as possible. I will encourage you since I'm going to be sitting right here next to the speakers, I will encourage you if we get in trouble to

speed things up. If I see there's a lot of discussion going on, I'll probably let that continue until it wanes some, but we do want to insure that particularly in discussions and questions and answers we have time to get that in for the NSET members.

Any questions from the speakers?

On this little item here, the change of sign, there's a plus. On that change of sign, you need to point it either down here or over here. This one is a little faster maybe. So it's up to you which way you want to use it.

So with that, we'll get into the agenda from the NEHI research areas, and first will be Dr. Dianne Poster from NIST.

DR. POSTER: Well, thank you for the introduction and the opportunity to speak today.

Evaluating the effects of nanomaterials on the environment and on human health requires a large amount of information, specifically with respect to the nature and properties of nanomaterials and a broad array of tools and analytical methods is necessary to gain this knowledge.

Thus, research on the development of instrumentation is crosscutting to many of the research needs that are identified in the research

needs document. Further development of existing tools or the creation of new instrumentation or approaches may be necessary, and key to these tools and approaches is metrology, which is the science of measurement.

The research area instrumentation, metrology and analytical methods identifies research to enable new instrumentation and standard reference materials and data that are in support of standard measurement protocols. These are to detect and characterize nanomaterials and also to measure the physical and chemical properties of nanomaterials, the not only environmental and biological matrices, but also the work place.

In addition, this research area identifies terminology, nomenclature, and standards.

This research area identifies nine research needs. Five of these can be grouped together in an integrated approach that is necessary to essentially understand, predict, and quantify the physics and chemistry of nanomaterials, as well as their behavior.

These five needs include the development of methods to detect the type and amount of nanomaterials in the biological matrices, the

environment, and the work place, as well as the development of methods to characterize and understand the physical and chemical properties of nanomaterials and their behavior.

In addition, the development of reference materials is a global approach that supports all of these research areas and helps to assist with assessing the quality and comparability of results from the analytical characterizations or the physical property characterizations of nanomaterials.

The other four methods identified here on the bottom are in support of this entire integrated approach. For example, the development of measurement tools to characterize the shape, structure, and surface area, or the development of standardized approaches to determine the purity and heterogeneity of nanomaterials are in support of the development of methods to understand and characterize the physical and chemical properties of nanomaterials that fall within this integrated approach.

In addition, the development of an inventory of nanomaterials facilitates the compilation of specific descriptive information of nanomaterials, for example, structures or properties that may be obtained using various analytical approaches, and this

greatly facilitates the development of instrumentation.

Also, basic terminology and comprehensive nomenclature of materials is necessary, for example, to unambiguously compare nanomaterials or products that might contain nanomaterials. So the development of a common language not only facilitates this type of comparison, but also supports all aspects of the measurement processes.

Today I'd like to provide an overview of these five areas, all nine of the means are described in detail in the research needs document.

Research need one is to develop methods for detecting nanomaterials and biological matrices, the environment and the work place. Evaluating nanomaterials requires knowledge of not only the nature, but also the properties of nanomaterials and validated assays are necessary to detect nanomaterials in not only animal and plant and food related matrices, but also tissues, and not only the detection of the nanomaterials themselves is necessary, but also the residues.

Validated assays will produce results that are very critical for assessing associations between specific nanomaterials, behavior, and possible

effects. This is a crosscutting research need that is essential to all of the areas that are identified in the research needs document.

Currently methods for detecting nanomaterials in the environment and in people are lacking, and in cases where methods are available, limitations of those methods and also the specifics within the various matrices have not been well examined.

Research need two is to understand the effect of modifications on the properties of nanomaterials. Modifications occur to nanomaterials during the production of products, and these modifications may affect the toxicity and also the biocompatibility of nanomaterials, as well as the material's ability to disburse or agglomerate, both of which may also influence toxicity.

Also, modifications may affect changes in behavior. For example, their uptake or degradation in biological matrices may be affected or also their usefulness may be affected.

Modifications may also affect the actual measurement process. Currently it's necessary to understand the effects of the modifications of nanomaterials because currently it's very unclear how

these modifications may affect the biological matrices.

In addition, existing methods that are used to analyze the chemistry of materials at either the micro or the macro scale may need to be adopted with changes or modified or enhanced in order to apply these methods to the nanoscale regime and procedures may change with a given modification.

Research need three is to develop methods for standardizing assessment of particle size and distribution. Both of these parameters are extremely important for understanding nanoparticle toxicity and accurate sizing is critical for understanding the amount and the number of particles in any given space or time.

Current methods for sizing particles below ten nanometers are very inadequate. There are a number of approaches that are available. However, these are very indirect in that they only produce population based sizing information.

In contrast, other methods, such as microscopy approaches, may produce direct sizing information. However, these lack sufficient throughput and also fail to produce population based sizing.

And, moreover, there is a significant lack of correlation between these types of approaches and the results that come out of these approaches and this research need addresses this issue.

Also, standardizing assessment of particle size and distribution will also greatly enhance our ability to define size parameters and also terminology.

Research need four is develop standard reference materials for the chemical and physical characterization of nanomaterials. Standard reference materials are stable, homogeneous materials that are well characterized for specific chemical or physical properties, and they facilitate with assisting researcher, laboratories and also industry with evaluating the quality and comparability of performance and analytical measurements of either chemical composition or physical properties.

Materials are also widely used for research applications. For example, they may be used to evaluate sampling instruments or devices that are used and also they can be applied to toxicity studies.

Currently there are very few nanoscale reference materials that are available, and the ones that are available may not be relevant to the

environmental health and safety research needs for nanotechnology.

The use of reference materials ultimately assists with the comparison of results.

Research need five is to develop methods to characterize a nanomaterial spatio-chemical composition. This is a critical parameter that also addresses many of the other research needs already identified, for example, the modifications which were described for research need two. This is a critical parameter for not only understanding the toxicology of nanomaterials, but also their properties and behavior and also their impurities that might be present and also defects.

Currently most chemical analytical techniques that are used are designed for bulk chemical composition and they lack the spatio-chemical composition that can be applied to the nanoscale in order to determine the chemical composition of these materials, and that is what this research needs address.

Approaches to characterize the chemical nature of nanomaterials are very challenging and currently are not well developed.

With that I'll conclude with this list of

questions that are applicable to this research category, and I thank you for your attention.

(Applause>

DR. ALDERSON: The next research area in the document is nanomaterials and human health, and Dr. Sally Tinkle from the National Institute of Environmental Health Sciences will present that.

DR. TINKLE: Thank you very much.

It's a pleasure to be here today, and it was a pleasure to work on this document with all of my colleagues from all of the federal agencies that contributed. Nanomaterials and human health is a topic of great interest to my institute, as well as to other -- okay. There we go.

This is the third chapter in the federal research needs document, and it addresses the -- I'm going to just use the side here -- it addresses the -- (pause in proceedings).

It focuses on three aspects: the biological response to engineered nanomaterials and their byproducts. Because nanomaterials have such potential value for industry, consumer and medical applications, it's important that we understand both their biocompatibility, their physical-chemical properties that are compatible in biological systems,

as well as their toxicological properties that may cause adverse health effects.

The third component of this chapter discussed toxicity screening methods. It's important for us to validate traditional screening methods and determine if they're adequate for a nanomaterial evaluation, and to develop new tests where they are needed.

The goals for the human health research strategy -- these are three overarching goals that you will find as you read through the chapter -- is to understand the relationship of the novel physical-chemical properties of engineered nanomaterials to their biological response, and the relationship of that biological response to human health.

This information can be used to develop predictive models, physiology based, physical-chemical models that will help us better design new materials and evaluate new materials, and overall these two goals then support development of biocompatible nanomaterials for medical, industrial, and consumer applications.

I'd like to look at two background concepts before we proceed to frame the research priorities that you will find in the federal research

needs document. The first addresses primarily the first research goal of linking exposure to body burden and biological response.

I show here a diagram that I've adapted from the National Research Council document from 1987 that shows the relationship, a linear relationship of environmental exposure to external contact to internal dose and biological response. This is a more detailed framework in which to understand the research needs that we're going to be able to discuss and to look at the adequacy of our research needs assessment in light of these steps in this framework.

While this is a fairly linear diagram, the research itself is a much more convoluted and complex structure, and I think that's important for us to remember. Biological research can be very complicated. We tend to have individual projects that move forward, as shown here by these arrows in a related yet individual manner.

As research develops and data become available, that data feeds back onto the original hypothesis which then can be modified or refined. There can be additional data, shown here by the blue and purple arrows, which feed into an ongoing set of experiments or ongoing research priorities that may,

again, modify or improve the research strategy.

What's important to remember is that although this is a complex and integrated process, the overall momentum for production of research data is a forward momentum.

So with these two concepts in mind, I'd like to look at the priorities we established in the federal research needs document in two categories. The first tier priorities identify the generalizable characteristics of toxicity and biocompatibility, and we've identified five specific areas. These are broad conceptual areas. The federal research needs document has increased granularity over and above what we're presenting today, and when we call for research to actually be done, the granularity increases even further.

So looking at these broad topic areas, we first want to understand the relationship between exposure, uptake, and body burden, and the relationship of absorption and transport of nanomaterials to the body.

This relates to the left-hand side of the diagram I showed you, what are we exposed to? How much does the body take up? And what is retained in the body versus what is excreted? How does the body

handle that material?

We want to relate these measurements of dose, this understanding of dose to the biological mechanisms at the cellular and molecular and systemic level within the body, a very simple way of calling for extremely complex research. It's basic toxicology of dose and response here in a little bit more granular discussion.

The final two bullets relate to some of the topics that Dianne discussed in her presentation. We need to evaluate our methods to quantify and characterize the exposure in the environment and in biological matrices in the human body. We need to look at the methods we have available, their adequacy, sensitivity, and develop new methods as necessary.

Additionally, we need to evaluate our traditional testing paradigms, our in vitro and in vivo assays and look at their validity for nanoscale materials, for measuring nanoscale materials accurately and do that both in vitro and in vivo.

So these basic research points will provide us with the data that we need to begin to understand the biological response to the novel physical-chemical properties of nanomaterials.

Looking at this in terms of the framework

that we discussed in the previous slide, you can see that the quantification and characterization of the materials for the environment cover the environmental exposure and external contact.

In the central part of the framework, we move into internal dose and biological response when we quantify and characterize the materials in their biological matrix.

Internal dose is supported by further research on absorption and transport through the body. How much got in and where did it go? How much stayed?

And then we can begin to piece together the relationship between exposure, uptake, and body burden.

While these experiments are occurring, we can also begin to investigate the mechanisms of interaction and begin to study the entire framework from one end to the other to give us that basic dose response research that we need.

The second set of priorities, they're considered a separate set because these are research priorities that are in many respects dependent upon the data, the results from these first experiments understanding generalizable toxicity, and as we go

through them you'll see why.

The first is to look at the relationship between [the nanomaterials] and the matrix in which the nanoscale materials are imbedded, and s the byproducts in that material and the use of that material as a delivered or absorbed dose.

So in the first set of experiments we're looking at the particles. Now we're looking at a more complex system that contains nanomaterials, a further level of complication.

The first set of data implies acute exposure, short term exposure, and the second set of priorities, we will use that knowledge then to move forward and study chronic exposures and implantable nanomaterial devices. This is of great importance for medical applications, drug delivery systems, implantable hips, pacemakers, et cetera. So we can move, again, to a higher level of complexity in the research.

Also, for the development of predictive models, of biocompatibility and toxicity, can we take the data from the first set of experiments and use it to identify crosscutting principles that will help us understand what makes a material compatible with biological systems or not, and can we predict that in

silico, [that is, in computer simulations].

There are also multiple databases in existence, occupational environmental particle health effects databases. Norris referred to these in his opening remarks, and these need to be examined carefully to understand them as predictors of health effects and to look at, again, leveraging existing data.

These priorities now map onto our framework. You can see that we move down from the first set of experiments to more complicated research, again, covering the paradigm, the framework from exposure and dose through more complicated studies of biological response.

We moved that into a final phase in which we have a research priority that compiles the data that we've accrued into some kind of data sharing framework. We need to be able to bring these data together in order to identify crosscutting principles and then move those crosscutting principles from data sharing into predictive models.

So you can see as you go through the chapter that we have used a general framework to cover exposure through biological response and then move it forward into predictive modeling and promote safe

development of nanomaterials.

So with that I bring forward the same concluding slides where we ask for your comment and input into this work.

Thank you very much.

(Applause.)

DR. ALDERSON: Our next speaker will be Dr. Phil Sayre from the Environmental Protection Agency, [who will present] nanomaterials and the environment, which is the third area.

DR. SAYRE: Thank you, Norris.

Good morning. Thank you for all coming. This is one more piece of the research strategy here. This one principally refers to nanomaterials and the environment. So this is the one that covers both effects on biological receptors in the environment and higher level effects as well issues having to do with fate of nanoparticles and the environment.

I want to thank the members of the interagency group that worked through NEHI to come together and synthesize some of these items that were in the NEHI document that you have into about six or so research areas that I'm going to present.

So nanomaterials in the environment is comprised, as I mentioned, about looking at ecological

receptors and ecosystems, which is essentially the hazard identification portion of the risk assessment paradigm that Sally also referred to. We're covering the hazard identification portion here under these six research areas, as well as factors that deal with essentially the fate or exposure to nanomaterials and the environment, of course, with the overall goal of assessing the risk of the material. So all of these fit within the general framework of the NAS paradigm.

Now, there are a few additional considerations. One of the areas that was identified and was identified as quite high priority was development of standardized sampling methods, relevance to nanomaterials in the environment, and this was actually covered in Dianne Poster's presentation on instrumentation in metrology.

I'm not going to talk about it anymore here, but it is viewed as being a key part of this research area as well. However, it fits better into the crosscut.

So what I have left here to present today are about five areas under environmental research concerns that I'm going to talk about. They're split, as I mentioned, into two effects areas, concerns, and three exposure oriented area for research.

So one of the other things that one could think about, and this was alluded to in some of the earlier slides as well, is what nanomaterial do you actually look at. Do you look at the material as manufactured? Do you look at the material as modified in the environment, or do you look, for instance finally at any sort of byproducts that are caused by the nanomaterial interacting with chemicals or other components in the environment, environmental matrices?

So throughout the five research areas tat I'm going to present on both effects and fate, the general feeling is that all three of these aspects of form of the nanomaterial and its interactions with the environment are important to bear in mind.

So as I mentioned, the first research area is an effects oriented research area. It's to understand the applicability of testing schemes to determine effects in individuals of a species. So this includes both, of course, aquatic and terrestrial species, and to look at testing schemes, which are generally used by regulatory agencies to evaluate commercial materials, drugs and chemicals.

Testing schemes generally are in a tiered fashion going from simpler tests to potentially more complicated tests.

Along with those testing schemes, of course, are associated test protocols that need to be examined. You're looking, of course, for toxic effects, but also you're looking for factors such as bioaccumulation, absorption, distribution in metabolism and excretion, and hopefully the amount of data that you get eventually allows you to develop things such as structure activity relationships in which you have enough data on a particular class, for instance, of chemicals in the traditional sense or in this case of nanomaterials such that you're able to actually predict the toxicity of the material based on those algorithms.

So this is the one component on assessing effects on individuals of a species. Now, the second component of the effects work here covered under research area two is to, of course, evaluate the effects beyond individuals of a specials, and that would include, of course, effects on biological receptors at the population community or ecosystem level. So going one step up from simple, straightforward lab tests that quite often comprise sort of the base set area of a tiered testing scheme.

Typically, for instance, for environmental effects work, EPA will look at things such as effects

on daphnia algae and fish for fresh water exposures.

And then going beyond effects on biological receptors, one needs to consider effects on other ecosystem components, biological components, such as nutrient cycling.

So this area then captures the second component of the effects research that's felt to be pertinent for environmental research.

Now, moving away from the effects research, I'm going now to exposure related research and one of the items that was identified of three is to understand the transformation of nanomaterials under different environmental conditions.

So the concept here is that if you understand the form of the nanomaterial in the environment, you might be able to better predict a number of things, including aspects such as transport of the material, and exposure factors.

So this sort of work would involve laboratory based and potentially pilot studies in the field for nanomaterials so that you get a better understanding of their transformation and, of course, degradation in the environment.

The sort of research studies on transformation have been coming up, for instance, in

the literature very, very recently. There was a study of an engineered nanomaterial in the environment, a multi-walled carbon nanotubes which appeared to actually become quite solubilized with organic material derived from river sediments, and that wasn't necessarily really expected, and the degree of solubility was apparently actually higher than what would be expected by taking those same multi-walled carbon nanotubes and placing them in conjunction with detergents.

So that was a little bit of a surprising finding, and of course, from that sort of example you can understand how transformations and other interactions between nanoparticles and the environment could affect aspects such as transformation and, of course, transport of nanomaterials.

So moving from this research area on transformation, the next research area, essentially factors affecting the environmental transport of nanomaterials does build on information gained from research area three on transformation.

And what we are looking at with this kind of research is really to be able to both understand and predict the transport within all environmental media. For instance, that example I gave on multi-

wall carbon nanotubes might imply that carbon nanotubes in association with organic matter might move a bit more than expected in, say, a lentic environment in a river system.

So to understand is one thing. To predict is another. Again, this links back to the earlier discussion on effects about structure activity relationships and being able to predict.

So first you need to understand. Then it's very helpful to be able to predict once you have enough information.

Now, the same issue, understanding a predicting also applies, of course, to partitioning between the various environmental media. One of the aspects here, of course, is that you want to understand where the nanomaterial actually is going to principally reside in the environment. So hence you can figure out exposures a little bit better.

Now, a final bullet here is "understanding the effects of nanomaterials on transport and partitioning of other environmental chemicals," and there was, again, another recent publication that illustrates this sort of concern on what kind of insights you can gain.

There's a recent article on nanosized

titanium dioxide showing that that actually at least in the case of cadmium seems to absorb more cadmium than sediments derive from, say, river rind (phonetic) system.

So that was perhaps not quite expected and can lead to some different transport and exposure scenarios and possibly indicate other environmental receptors that might be more or less affected.

So this is research area four, and then there's one final one under exposure, if I can get this to work. There we go, and that is exposure on environmental receptors. Once you understand transformation and transport, it becomes a little bit more straightforward, perhaps, to understand the actual exposures throughout the life cycle of a material. So not just identifying sources of nanomaterials for manufacturing, but also understanding sources of nanomaterials and exposures as a result of use and disposal.

Other factors, of course, that are important and play into this are bioaccumulation, and of course, the relationship between environmental exposure and absorbed dose in the receptor.

So this essentially culminates a three-step process on the three different exposure research

areas, and of course, again, they were complimented by two effects oriented research areas.

And I will end my slide as everyone else did with looking forward to your comments on this research area.

Thank you.

(Applause.)

DR. ALDERSON: The next area is health and environmental surveillance, and Dr. Vladimir Murashov will make that presentation, and he's from the National Institute for Occupational Safety and Health.

DR. MURASHOV: Thank you for the introduction.

Good morning everybody. As it was mentioned just now, I will briefly describe your health and environmental surveillance section of the research needs document. More information about this area can be found in Chapter 5 of the research needs document.

This area of research needs will focus on both incidence of specific adverse human and environmental health outcomes to identify risk factors and also on specific risk factors in order to identify adverse human or environmental health outcomes.

In the document, there are 14 research

needs identified. There is some overlap within that research area and also with other research areas. For example, a research need identified as "develop methods for measure in nanomaterial exposures in environmental matrices" falls on the research needs described in "instrumental, metrology, and the analytical methods research area."

And also, a research need identified as "determine environmental faith and effects following known or suspected releases, for example, overlap significantly with research" needs identified in nanomaterials and the environment research area, which was just described.

In my talk today, I will use the risk assessment framework to structure my presentation. As you know, in this framework there is hazard identification and exposure assessment [elements], which will provide us with information to conduct risk assessment.

In the health and environmental surveillance area, we need both hazard surveillance and exposure surveillance in order to contribute to the quantity and qualitative risk assessment as well as to ultimately contribute to the reduction of risk uncertainty.

The document "hazard surveillance and exposure surveillance" describes three major populations which are potentially exposed to nanomaterials and where exposures can be quite distinct and unique, those workers, general population and the environment.

So I will start with hazard surveillance needs. In this part of my talk, the first research need that I will mention is "collect health information." This research area includes both passive and active health surveillance, and will look not only on sentinel events, but also will include studies to test hypotheses through, for example cohort studies.

Conducting research in this area will help reduce uncertainty about risk through quantifying human health risks associated with exposures through providing feedback on the effectiveness of risk management programs and through guiding future research activities.

It could also help with identifying unexpected adverse health or environmental effects.

Our next research need is described as "analyze injury and illness reporting." It will focus on evaluation of existing occupational and consumer injury and illness reporting programs. Addressing this

need will aid in identifying adverse outcomes associated with nanomaterials. It can be simple to implement and less costly, given that such programs already exist.

The next research need described is "gain early knowledge of unanticipated effects to biota." It will focus on collection, counting, and evaluation of specimens and habitats affected by nanomaterials to identify any abnormalities, and it will provide earlier information about unanticipated behavior of nanomaterials in the environment.

The second part of this presentation will list research needs which fall under the exposure surveillance area.

The first research need described [in this area] as "collect exposure information" will look at both quantitative and qualitative data on nanomaterials in the work place and other indoor and outdoor environments. Addressing this research need will develop data, support interpretation of work place and environmental information, and it is important for risk analysis, research prioritization related to biological effects and planning. It will also help to establish where exposures have occurred as a result of nanomaterial release.

Again, it might be possible to use existing monitoring programs that can hopefully help save some resources.

Similarly for the environmental area, the next research need which is described is "establish environmental monitoring activities." This research need will focus on surveillance of air, water, soil and sediments to establish environmental exposures resulting from non-material use and release, and similar to previous research need, it will help with prioritizing research and promote early prevention activities.

Specifically for the workplace, the next research need, which is described as "understand work place broad decision factors that determine exposure to non-materials" will help not only to understand behavior of non-material in the workplace and factors that determine release and resultant exposures. It will also help with reinterpreting existing monitoring data and identifying exposures that have not been monitored before.

Similar to previously described research needs, addressing this need will result in the reduction of uncertainty. It will provide information on exposure potential for workers, general population

and environmental species, and it will aid in planning risk management programs.

Next, the research need focuses on general population and it is described as "quantify nanomaterial exposure to the general population from consumer products, industrial processes, and products containing nanomaterials." It will focus on intentional and unintentional exposures to nanomaterials in the general population, resulting from production and use of nanomaterials.

Addressing these issues will help to quantify human exposure resulting from use of nanomaterials in the consumer products and from industrial releases that result in contamination of the environment.

The next research need, actually, the next several research needs will focus on identifying populations which are potentially exposed to nanomaterials, and in this way it will allow us to target our resources.

For example, this research need is focused on human population groups potentially exposed to nanomaterials, such as workers, patients, consumers, and people living around nanomanufacturing facilities. Addressing this research need will help to identify

target populations, and in this way it will help to conserve resources and focus epidemiological and intervention studies.

It will also ultimately help to improve manufacturing to make it safer and also improve utilization of nanomaterials in consumer products.

Okay. This research need similarly tries to identify target population within the environment. It is described as "evaluate release scenarios most likely to create environmental exposure", and again, similar to the previous research need, it will help to focus environmental surveillance activities.

And I would like to conclude like all previous speakers did with this slide, which lists the questions that we hope you will help us answer in order to improve our strategic plan.

Thank you.

(Applause.)

DR. ALDERSON: Our final research area is on risk management methods. Dr. Rick Canady from the Food and Drug Administration will make that presentation.

DR. CANADY: Good morning. I've been doing an informal survey of the number of people intently studying the capillary structure of the back

of their eyelids, and it has risen and fallen a few times over the last hour or so, not associated with any particular speaker, but I want to give you the opportunity if you want to stand up, shake your shoulders, you know. Social permission is given because I think we have a good third of the research needs to go through within the risk management chapter, and I want to get your attention. I want to make sure we get some good feedback on this. So could you please wake up?

(Laughter.)

DR. CANADY: Thank you.

I'm Rick Canady. I'm with the Food and Drug Administration, and if we can go to the first slide, please. The next slide, rather.

So, again, the research needs chapter for risk management methods is 13 pages of this document. It is the longest chapter. It has the most research needs. It has fully a third of the research needs. It is split into several different categories, and this is the same introductory box that's in the front or the chapter for Chapter 6 that the other four speakers have just shown to you.

But I've split it out a little bit to help you understand it. One of the areas that we cover

within the chapter is how to reduce exposures, research on risk management methods regarding reduction of exposures, particularly to nanomaterials.

Improving procedures for risk and accident avoidance is a big area that we need to consider obviously for nanomaterials that may have unique characteristics. Improving work practices, engineering controls, protective equipment and so on is another large area that we need to consider specifically for nanomaterials.

And within the risk management research needs chapter, we also included life cycle assessment as a way of looking at where within the product cycle exposure potential, hazard potential may exist.

You'll note that there's overlaps with some of the other speakers and some of the research needs in our other chapters, but it's in this chapter that we've particularly paid attention to it.

Again, 24 research needs are identified in Chapter 6. I'm going to use some major themes in order to help you walk through those research needs. Unfortunately, because of the large number of research needs, I'm just going to give you the highlights. I'm just going to give you the bullets of the identified research needs. We won't have time to go into

rationale, scope of the individual research needs, and so on, but hopefully through the organization I can help you see or at least give you an overview and help acquaint you with that chapter for your aid in providing comments to us.

There's overarching concepts within the first chapter of the document though that do apply to risk management methods, and one of the first and most obvious, but one that may perhaps be overlooked at some times, is that good risk assessment is essential for good risk management. If you don't have the good foundation materials to help you understand what needs to be managed, you're not going to do a good job in managing the risks.

A second is that research and the information generated through the research is itself an integral part of risk management. Sally Tinkle in her presentation made a point of this in showing the recursive loops with regard to developing hypotheses and developing information regarding the risks, and it's just important to keep that in mind, that risk management includes research.

And a third point, and this was pointed out early in the presentations in Dr. Alderson's presentation, for example, is that we really need to

think of risk management as an adaptive process for nanomaterials because the evolving technology is necessitating that. We don't know enough about what we're going to know in ten years in order to establish procedures now that necessarily cover everything we're going to need to cover.

I want to make an additional point though while we're in background that we're talking about risk management methods research that is specific to nanotechnology, and for that reason there is discussion within this chapter that focuses primarily on exposure avenues, for example, and life cycle assessment and hazard avoidance, and so on.

But I don't want to lose sight of the fact that this fits in the usual larger context for risk management, which is this cycle of engaging stakeholders, developing risk options, decisions, actions, evaluation, this whole cycle which was in the presidential, congressional Commission on Risk Management or risk assessment or risk management report back in '97. It's this framework in which this all fits.

And, again, we're talking about research methods, for nanotechnology not specifically about changing how we do risk management per se.

There's a general theme that we pulled out from the research needs within the chapter that was useful to think of as an overall approach to risk management methods, research needs, and that is we need to evaluate the appropriateness and effectiveness of current and emerging risk management approaches for identifying those nanomaterials with the greatest potential risk.

And you'll note, again, this is focusing on the specific things that have to do with nanomaterials and specific things that have to do with risks and exposures to nanomaterials.

We thought in order to present, again, the 24 research needs within the document that it would be useful to talk about major themes that flow through the document within Chapter 6, and I have five of them here.

The first is understanding -- and I'll have organized the research needs within the chapter along these themes in the subsequent slides -- the first is understand and develop best work place processes and environmental exposure controls.

The second theme is "examine product or material life cycle for risk reduction choices," and again, we talk about within this life cycle analysis,

and also things akin to green chemistry approaches to developing materials.

There's a need to develop specific risk characterization information that allows classification for hazard properties again specific for nanomaterials, develop trend information so that we understand where to apply resources for evaluation of nanomaterial risks and their management, and then we need to address the question of whether there are specific needs for risk communication with regard to nanomaterials.

Within the first theme, understand and develop best work place processes and environmental exposure controls, and again, these bullets and subbullets here are the actual headlines within the document of Chapter 6 that are the specific research needs in the document, and I'm trying to walk you through those so that you have a familiarity of them as you provide comments to us today.

The first bullet under this theme is "evaluate accepted risk management approaches for nanomaterials." In other words, look at the ways that we look at risk management methods or we approach risk management at this time and ask the question: for nanomaterials are new approaches needed?

The second bullet, evaluate opportunities for greatest potential for risk reduction through minimizing hazard of exposure to nanomaterials.

A more specific bullet, understanding the efficacies of personalized protective equipment, and I'm probably getting that acronym wrong, but PPE, suits, respirators, things like that, hoods and so on, against nanomaterials as exposure and hazard information evolve, again, speaking of the adaptive management nature of this problem.

We need to improve understanding of the unique challenges for process design, engineering control systems, applied to engineered nanoscaled materials, particular with regard to air and work place exposures at this point.

And I apologize that I'm going quickly through this. This is, again, to orient you to what's in the document rather than to provide full detail of the scope and rationale of each of these.

Again, within the first theme, understand and develop best work place processes and environmental exposure controls. An additional research need is understand the role and effectiveness of work practices and administrative controls in reducing exposures to nanomaterials as exposure and

hazard information evolve.

More specifically, with regard to accidents and work place issues, spill mitigation technologies and risk management procedures specific to nanomaterials.

Identify and evaluate appropriate packaging for nanomaterials. Are there specific needs for nanomaterials with regard to packaging?

Develop filters and fabrics with improved capturing and regenerating, self-cleaning capabilities, and again, these are all with respect to understanding and developing work place processes and environmental exposure controls.

The second theme that we identified was examine product and material life cycle for risk reduction choice, and within this we're wrapping both life cycle analysis, as we typically understand it, and also sort of green chemistry approaches to developing the materials, nanomaterials, with known and manageable risks in their profiles.

So understanding the efficacies of PPE against nanomaterials as exposure and hazard information evolve, this overlaps with the previous theme in the sense that we're talking about effectively work place controls, but the focus here is

on understanding where in the life cycle or the use of a product that opportunities for exposure with existing personal protective equipment might occur. So that's the nuance that's different in this theme.

We need to improve the understanding of the unique challenges for process design and engineering control system applied to engineered nanoscaled materials in the air.

Understanding how life cycle assessment might be suitable and adaptable to engineered nanoscaled materials. And, again, this is worded in the sense that we need to consider nanoscaled materials specifically. There isn't a need to evaluate life cycle analysis independently of nanoscaled materials. That's not what's spoken to here, but rather, it's about what's necessary for nanoscaled materials and determine stages in a product's life cycle that introduce the greatest potential for risk.

Theme B continued, and there's fewer with Themes C, D and E. So we're going to move through this rather quickly.

How am I doing on time, by the way? Five minutes.

Determine whether any residual

manufacturing wastes of concern are being created, and if so, which processes are associated with such waste. Where wastes of concern are being produced, determine the best methods for waste disposal. Develop environmentally benign manufacturing processes that can reduce potential impact of nanomaterials.

Again, this gets to both the life cycle analysis and the green chemistry approaches to nanomaterials.

Can somebody answer the phone there?

(Laughter.)

DR. CANADY: Research Theme C gets largely to the point that we have a need to consider the information that may need to be developed for hazard characterization. For example, in transportation of nanomaterials and so on. So we need to understand factors influencing flammability and reactivity. We need to in a sense fully characterize the nanomaterial with respect to hazardous properties, and again, this overlaps with what was discussed in earlier chapters, for example, Dr. Sayre's, Dr. Tinkle's chapter, and also Dr. Murashov's chapters. But it has the intention of going more specifically at managing those risks rather than identifying the full nature of the risk.

Research Theme D, develop trend information to help us focus research efforts, and this gets to the point that in order to understand where to focus our risk management efforts, and more particularly our risk management resources, research resources, we need to understand where nanomaterials are in the economy, where they are in use and so on, in order to be able to most appropriately focus those resources.

So we need to understand the flow of nanomaterials through the economy and ultimate disposition, understand the use of nanomaterials and products, and discern trends in effects or causality with respect to nanomaterials. And this gets to what Dr. Murashov was talking about with regard to surveillance. Obviously there's some overlap with the two themes.

And the final research theme, "develop specific risk communication approaches and materials for nanomaterials," and again, I want to emphasize that we're not talking about reevaluating how to do risk communication here necessarily. We're asking the question: for nanomaterials are there specific risk communication needs that we need to consider for nanomaterials?

Evaluate whether current risk communications are adequate for known risks and for risks that can be anticipated. Where necessary develop effective methods to communicate risk or safety information to potentially affected population and determine how best to communicate the hazards to the emergency response community under real world accident scenarios.

That was the last of the research themes. Each of us has presented this last slide as a way to help focus you on what we'd like to hear from you. We'd like to ask you is the breadth of the research category, in this case the research management methods captured by the research needs that we've identified in the chapter.

What criteria should be used in setting research priorities? Which research needs should be prioritized with what's in this category? And of course, the catch-all, if you have any additional comments.

Thanks very much for your time.

(Applause.)

DR. ALDERSON: I would like to thank the five NEHI members for both their presentations and they've kept us on schedule.

We had a lot of conversations in the last two days about this schedule and making sure that we stayed on schedule. So, again, I thank you all.

Well, it is time to move to the real meat of today's agenda, and that is to hear from you, and we have 11 speakers who signed up in the pre-registration mode to speak today, and each speaker will have 15 minutes and that will be followed by a ten-minute question session. I would ask all of the NEHI and NSET members to come on down to the front for this session so that we will have a microphone available for you during the questioning sessions.

It is very important that we hear from you, and I don't think any of the NEHI members can emphasize that enough. We really need to hear from you on the subjects, and you have heard that five times in the previous speakers, what we want to hear from you, and so we are serious about this.

So I think it is time to get started. Our first speaker is Mr. Peter Linquiti from the ICF International.

MR. LINQUITI: I think Vladimir figured out how to do this best, which is to point this [remote] that way.

Well, I would start by thanking you all

for the opportunity this morning to come and offer our comments on federal efforts to understand the EHS implications of nanotechnology.

By way of introduction, my name is Peter Linquiti. I recently retired from ICF International after a 23-year career that focused on environmental policy and economics, and now I'm a consultant to ICF working on their nanotechnology program.

For those of you who may know not ICF, we've been active in the environmental arena for the last 30 or so years and provide policy and technology consulting services to a full range of commercial and federal clients. To give you a sense of our size, it's about 1,800 people in total at ICF.

My remarks today are going to be primarily drawn from a study that ICF did toward the end of 2006 looking at this very topic of the federal effort to better understand the EHS implications of nanotech. I'm one of the co-authors of that study. Adam Teepe of ICF is my fellow co-author sitting in the audience here, and if you are interested, he does have extra copies of the report.

The methodology we employed was pretty straightforward. We did a literature review, and then we also interviewed several stakeholders who are

involved in the issue -- both within government in the legislative and executive branches, as well as NGOs, and in the corporate sector.

This was pro bono work done by ICF, meaning there was no particular client paying for the study. Rather, ICF commissioned the work in order to enhance its own intellectual capital and to make a contribution to the policy dialogue on what we see as one of the most important environmental issues that's on the agenda today.

The report is about 30 pages long, and I won't try to cover it in its entirety. What I've done is try to pull out a few of the highlights that I think are particularly relevant to today's topics.

I'm not going to hold you in suspense. I am going to go straight to the conclusion of the report, and it is essentially that, when you step back and think about the purpose of the federal research effort here, it is to better understand the EHS implications of the nanotechnologies that are coming to market so that we can make better decisions -- both in government as regulators or in the private sector as EHS officials responsible for safe handling of these materials.

So what that suggests to us is that, as

important as the quality of the science is, equally important is the management framework that is brought to the federal research effort to assure that we've aligned the research with the needs of the decision makers. That ultimately, research that does not serve the purpose of helping a federal policy maker make better policy or a corporate EHS official do smarter things in the work place with respect to nanotechnology, that research is perhaps interesting. It's perhaps valuable. But it's not interesting or valuable in the context that we're talking about here today.

The focus really needs to be on actionable knowledge that can make a difference in how we steward nanomaterials as they come to market.

We've picked out five management principles, business processes, if you will, from the report that we think are most important, worth highlighting here.

The first -- and other speakers have already addressed this and I applaud them for doing so -- is to recognize that we're not engaged in a one-off effort here in 2007. We're talking about a series of technologies that will play out over a time period measured in decades. Mike Roco's work suggests four

generations of technologies that move from the current passive nanostructures onto the more complex molecular nanosystems.

Each one of those generations -- we believe -- will pose different EHS questions, and as a consequence, the research agenda has to be able to keep pace with the evolutions in the technology.

I think a second evolutionary driving force that we've got going here is the scientific process itself. As cumulative work is done and we build a body of knowledge that gives us insight into the EHS issues associated with nanotechnology, what might be on the frontier of scientific uncertainty today may be old hat and a completely resolved issue three or four years from now, and we might have new scientific issues that are going to be at the forefront.

So the combination of the changes in the technology and the accumulation of scientific knowledge means that we have to put in place not just a one-off strategy here in 2007, but to build a mechanism that can sustain itself, refresh that agenda over and over the next couple of decades.

Along those lines, the second principle we're suggesting here today, and again, this is

somewhat similar to remarks that have already been made, is that the research agenda is an integral part of the overall risk management process. Research is done in order to inform risk assessments which can then help decision makers make risk management decisions.

And we believe the concept essentially of reverse engineering -- working backwards from the key management decisions that need to be made, through the kinds of risk assessments to support those decisions, and then on to the research that's needed to support those assessments -- is the correct way to frame the agenda.

We think it's very, very important that the federal regulators who have the statutory responsibility for protecting human health and the environment and ensuring occupational safety play a key role in setting the agenda. After all, they are going to have a primary role in making these risk management decisions. As I understand it, we're talking about the Consumer Product Safety Commission, FDA, EPA, and OSHA, and those folks clearly need to have a seat at the table and a major say in setting the agenda.

That's not to say that some things might

not fall through the cracks. We've identified what we call "orphan" risk issues that may not percolate to the top of the agenda immediately, and that's why meetings like today's are particularly important to look to other stakeholders to provide input. We have within the government some first class research operations at NIOSH and NIEHS who have an awful lot to add to the agenda setting process. We have corporate interests that might be expressed through federal advisory committees, like the NPPTAC over at EPA, or perhaps through trade associations like the American Chemistry Council.

The bottom line ultimately is we need to find a way to make sure that those orphan risk issues don't fall through the cracks. In that sense we're looking to folks outside the federal regulatory system to help us put those [issues] on the agenda.

The third management principle we'd like to touch on today, and again, it was mentioned a little bit earlier, is that a research agenda for EHS issues that's targeted at nanotechnology needs to get ahead of the curve with respect to product development and the introduction of new nano products into the marketplace.

If we don't find a way to get ahead of the

curve by a couple to three years and figure out what products are going to be in the marketplace, we'll inevitably be playing catch-up. We'll find out that products are in the marketplace and then realize that EHS research is appropriate. We think that's a lost opportunity to get ahead of the game and perhaps be a bit more proactive in setting the agenda.

Now, clearly, companies are very protective of their new technologies, and they're not likely to share them in great detail with outsiders, but we do think there are a number of tools that can be used, that need to be used to help put those issues on the research agenda, the first of which is that EPA has some considerable power under TSCA and FIFRA. I think they do need to be explored, and I know they are being explored as mechanisms for bringing information into NNCO and NNI to figure out what specific technologies belong on the research agenda.

I think that because nanotechnology manufacturers aim to sell their products, they're not keeping them a secret. We have found that if you pay close attention to the professional literature and you attend industry conferences in force, you can get some good insights into what's coming to market, not perfect insight by any means, but as a part of an

overall strategy, we think that kind of pre-market surveillance is important.

On this third point up here, we think it's not unreasonable to ask that the recipients of the billion dollar-plus R&D budget from the federal government, whether we're talking about extramural grant recipients or intramural government programs -- and I'm not talking about the EHS piece of this. I'm talking about the research that's being done and the technology development itself -- those folks have great insight into the development of many of the technologies. We don't think it's unreasonable if they're getting this much money to ask them perhaps on an every six-month basis to report to NNCO in a short, succinct way: This is what we see coming down the pipeline; these are the kind of technologies we see being developed or the applications to which they're being put.

And that would, again, help keep those technologies on the research agenda. I think there are also some great voluntary partnership programs that NIOSH and EPA are looking at.

In the NIOSH [program], in particular, you essentially can get some free consulting advice from Chuck Geraci at NIOSH, who will bring an exposure

assessment team to the plant and help you look at your occupational exposure. We're talking about a nanotechnology manufacturing plant. At the same time, NIOSH is also getting really important insights into the product pipeline, and we think that helps make NIOSH, for example, a great entity for providing input into what belongs on the agenda.

And then lastly, the United States is not the only government struggling with this issue, and through the OECD process and government-to-government contact, we think there could be insights gained about what the product pipeline looks like.

The fourth of the five management principles I wanted to mention is this distinction that lots of people like to make between applied research and basic research, with basic research being quite unstructured, less circumscribed, and that the research follows the findings, so to speak, and as discoveries are made, the next wave of research is teed up and launched.

Applied research is much more focused on getting defensible, credible answers to specific questions, and we think that it's very easy to fall into the trap of looking at the entire $1.3 billion federal investment in nanotechnology research and

development and assume it's more toward the basic end of the spectrum. It's our contention that essentially not all -- and if I had more time I'd get into the subtleties here -- but the vast majority of the EHS research really is applied research, and it needs to be managed as such.

And just quickly to go over a couple of the implications of what it means for EHS research to be applied: again, we're suggesting that the research needs to be very focused on specific questions. We'd like to see the research solicitors, rather than the researchers, have a lot more control over the framing of the research questions.

We studied a couple grant solicitations that recently have been put out on nanotechnology. They cover a very wide scope and they invite the research community to propose the topics to be studied.

This is an excellent approach when it comes to basic research, but when it comes to applied EHS research, we think it concedes a bit too much control of the research agenda to the research community. We would prefer to see research solicitations that are much more narrowly focused around specific risk management issues and the kinds

of research that needs to be done to support those decisions.

We think it's important that, along the way, the solicitor and the researcher collaborate. We are mindful of the need for scientific integrity and understand the risks if the connection between the funder and the grantee gets too close, but we don't believe that the current arm's length relationship between grant recipient and funder is entirely appropriate. We think that the grant recipients should be sharing information as it's coming out in their research. I know Nora Savage over at EPA does a great job of bringing in her STAR grant recipients to report on their progress.

We also think that as researchers need to make decisions -- as they're executing their research -- about which direction to go, it's entirely appropriate for them to solicit input from the funder who's back in the federal agency responsible for the risk management decision, not for a definitive decision about where to take the research, but at least to get that input.

We also think it's not unreasonable to set tight time lines and specific deliverables in grant situations. We, for example, think that it should be,

when we're talking about EHS research for nanotechnology, an explicit criterion in evaluating grant proposals as to how quickly the researcher can deliver the results.

Now, of course, we have to keep in mind that we need to make sure those claims of quick delivery are credible, and that we're going to end up with scientific work that has integrity, but we have good, strong peer review panels for grant applications. Assuming they'll be able to ferret those kinds of issues out, we think that the scheduling issues are ones that deserve a lot of attention.

We think ultimately there's a lot of capability to do research out there. There's no reason to restrict the research to any particular group of types of researchers: academic, contract research, other federal agencies. Everybody should, we think, have an opportunity to participate.

The fifth and final management principle that I wanted to get at is related to what we ultimately do with the knowledge that comes out of the research process. I showed you all -- but I didn't spend any time talking about it -- that circular diagram where we identify the right research that

needs to be done. We manage it effectively, and then we apply it effectively.

So this comment here, item number five, really goes to that third and final step. Research that's done well and is very illuminating is only valuable to the extent that it gets into the hands of the people that need to make the risk management decisions. Here we have in mind, really, a classical library model where you have librarians, science-oriented librarians, who are proactively monitoring the literature, finding out what's out there, and turning around and looking to their customers -- the users of the material -- and making sure they're meeting their needs.

We have a little graphic here which I won't sort of walk you through. It may not even be legible to you, but up there along the top row in blue are all of the sources of information. We think of the green thing in the middle as a hub, a true library where librarians are keeping track of the state of the literature, and then, in purple across the bottom, are the library users.

And we think it's important to view it as a hub like this rather than a portal. There are several great portals out there with lots of

interesting information. They're a bit ad hoc, but ICON, the Pew Center [Project on Emerging Nanotechnologies], and NIOSH all have good sources of information, but we think ultimately a single point source of information would be really invaluable in creating the kinds of flows of information that we're talking about.

So those really are the five principles I wanted to cover. They are recapped here on this slide just to refresh your memory.

Again, we think that this is not a one-off 2007 event. We are setting a research agenda that will last for the next several decades.

We need to constantly realign the risk research agenda with what's happening in the marketplace and the new products that are coming to market.

We always have to be informing the risk research agenda by the risk management decisions that need to be made.

We need to remember that EHS research is primarily applied research and that it needs to be managed as such.

And then, ultimately, the information that we generate through the research will only be valuable

-- the federal government will only get a return on its investment -- if we put that information into the hands of the people who need it, and that requires a knowledge hub of some sort that can bring all of this information together.

So that, in a nutshell, is what we think are the four or five most important aspects of the management of the effort, and with that I'll end there and take any questions that folks might have.

(Applause.)

DR. CANADY: Rick Canady with the Food and Drug Administration, part of the NEHI Working Group.

A question with regard to principle number two that you talked about, and that is -- let me recap it for you -- the research agenda should align with pending risk management decisions, and it has to do with the tremendously broad range of materials that we're talking about.

And I'd ask for your further thoughts about how we address prioritizing based on pending management decisions considering that very broad range so that we're not led by the flavor of the day. Orphan issues I understand, but if you leave things to what's on our agenda for today, you tend to be led by your nose, and I just wonder if you could comment on

that.

MR. LINQUITI: I guess two thoughts occur to me. The first is that in some cases regulatory agencies are driven by their statutory requirements to look at certain kinds of products coming to market. EPA's TSCA review comes to mind, and where there is a statutory obligation for EPA to focus on what comes in the way of premanufacturing notices. So to me that's one area where clearly, whether you think it's important or whether you think the exposures will be high or whether you think the hazards are going to be high, there has to be research to support that process under the statutory process.

I think the second piece of it, and a couple of the speakers earlier have already hit on this, you do need to bring in the two core principles of hazard and exposure and ask yourself, where is it most likely that we're going to see high exposures? Where is it most likely that we're going to see high hazard?

And that's inevitably a judgment call. I think that the more time you have to do it the better the judgment call, which goes to the point about visibility into the product pipeline, and if you can see something coming for two or three years, you have

some breathing space. If it's cosmetics or nanomaterials and cosmetics, gosh, you know, you don't have much breathing space. That's already an issue that the community is quite concerned about.

DR. ALDERSON: Sally.

DR. TINKLE: I'd like to follow up on your paradigm for accomplishing the EHS research. If I understood correctly, in your earlier slides you anticipate that most of these nanomaterials are industrial products, consumer products, et cetera.

Yet it sounds to me like you are asking the federal government to do the EHS research on industrial products. So could you talk a little bit about where you see the responsibility for EHS research?

MR. LINQUITI: That I think is an excellent question, and I think that leveraging corporate resources to do the EHS work is critically important. I think that manufacturers who want to bring product to market are very motivated to do what it takes to jump through the regulatory hoops to prove the safety of their product.

I also think in talking to lots of folks in the corporate sector there is a long range concern about product liability, and it's not just about

satisfying the regulator today. It's also ensuring that they have the information so that they can show their stakeholders that they've been wise stewards of the nanomaterials.

That said, there are some issues related to credibility and objectivity of research commissioned by the manufacturers. So I think if you go down that path there do need to be procedures in place, perhaps peer review procedures to assure that the research is up to snuff and can be a basis for making decision.

I think there's a philosophical, ideological question about who has the burden of proving the safety of products coming to market. The Europeans under the REACH Program may have taken a fundamentally different approach to that question than the United States has taken. That's above my pay grade.

DR. TINKLE: So are you coming down or trying to stay neutral on calling for the EHS issues to be handled through a regulatory mechanism, to make sure that data from industry are transparent or for the federal government to do the research so that it is transparent?

MR. LINQUITI: I guess to my way of

thinking the optimal outcome is a blend. I think that there are certain aspects of EHS issues that have such significant potential impact that we clearly want the government in its highly credible, objective approach to be employed. If we're into very specific, narrow EHS characteristics of particular products, if the work is done by the manufacturer and suitably peer reviewed, I think that's probably acceptable.

This work is very expensive, and it's also nice to get as much of that burden onto the commercial sector as possible.

DR. ALDERSON: Phil.

DR. SAYRE: Peter, I just want to follow up a little bit on that. I was kind of struck by your focus on identifying materials currently and in the future, and I think that has a lot of value in terms of what should be focused on by the federal government. Are you an advocate of understanding how to redo the testing protocols if necessary based on certain nanomaterials and then would your analysis of what's currently on the market or what's coming then fit into that general process of developing protocols that would be used for a broad array of nanomaterials as opposed to individual testing of nanomaterials?

I think you actually -- you actually hit

on that on one of your earlier slides, the idea of picking broadly representative materials. But I'm curious about the protocol side of it.

MR. LINQUITI: Sure. I guess I want to first start by caveating my answer that saying I'm not a scientist and I don't want to venture beyond my area of expertise. As I understand it, there are some foundational issues related to measurement protocols, testing and methods. That until those issues are resolved, till the research is done so that we have consistent and reliable approaches, we'll be moving in a very ad hoc way as we move forward in the research.

So I understand that to be kind of a very foundational place to start. Once that is put to bed, so to speak, I do think you want to turn to looking at those research topics that go along with nanomaterials that have the potential to pose the highest hazard, or exposure, or one times the other to get the highest risk potential, and look at it that way.

But I think there are, from what I understand, foundational measurement, methods issues that have to be resolved and resolved quickly.

DR. ALDERSON: Please.

DR. TEAGUE: Peter, I was very interested in your diagram about sort of the apportioning of

applied research versus basic research in the field of EHS research, and maybe you would see that as under the left-hand tail of your EHS research peak there. But where would you see such what I would consider to be as basic research, like predictive toxicology, the basic foundations of the structure-function relationships and things like that?

It seems to me like that that is -- maybe it is small compared to some of the others, but it seemed like that would be a very important component of the overall EHS research.

Any comments on where you see such, again, as what I would see as basic research fitting.

MR. LINQUITI: I'm really glad, Clayton, that you brought that point up, and I alluded to the fact that I was going to skim over it earlier, and it really would be a mistake to interpret my remarks as saying that all of the EHS research is applied in nature. I think there are clearly elements that have all of the features of basic research. And we need to remember that.

In part it's around the initial foundational work on methods and metrology and assays and the like. That is all very basic research.

I also think that in order to make sure we

don't inadvertently put our blinders on, there needs to always be an element of basic research in the EHS area that we don't get too cocky, assume we've got the questions figured out, and go down a really narrow applied path.

We've always got to have some kind of surveillance mechanism that says, "Huh, maybe there might be an EHS effect of this nanomaterial over here."

So, you know, if I had to balance it and maybe in the early years because of the foundational work that has to get done in the basic arena, you know, maybe it's 30 percent, 40 percent basic and the balance in applied, and then maybe once we get to steady state and we've answered a lot of those foundational questions, maybe it's 80-20, but there is a material amount of research we think in EHS that should always be basic.

But the point we just wanted to make is that there's really two sub-portfolios in the national investment, and that the $1.3 billion is two sub-portfolios really.

DR. ALDERSON: We have time for one more question. Anyone? Vladimir.

DR. MURASHOV: Thank you, Peter for the

very nice presentation. I just have a question about your position number three, where you say that the research agenda should have been formed by product development pipeline. Given that the nanomaterials can vary just dramatically in their chemical; composition, shape, functional groups and so on, even when you use, let's say, pre-market notification as a sieve to identify which products, which nanomaterials can end up in the market, it's still very difficult to choose the winners in the market, and even those products which end up in the pre-market approval stage might not be the winners, and you still end up with a huge amount of distinct nanomaterials.

Do you have any suggestions on how to identify which nanomaterials to study?

MR. LINQUITI: Well, I guess I would say, again, not being a scientist I'm not qualified to comment on the feasibility or the efficacy of grouping types of nanomaterials and studying them as classes and reaching conclusions that are broadly applicable to the entire class of chemicals that you put together.

But what I would say, again, and it's a pretty basic point, but I think it's just such an important one, is that whatever process we use, it's

going to be easier if we get started sooner, and if we have time to think about whether we can classify things together and whether they'll have like properties that can be characterized en mass, that's much easier to do if it's two years before the product is in the marketplace rather than in the marketplace.

I think you do make an excellent point, which is that if you wait until the stuff is in the marketplace, the winners have been picked and then you know what products need to be researched, but perhaps that's after the horse is out of the barn. It might be a little too late at that point.

DR. ALDERSON: Thank you, Peter.

MR. LINQUITI: Sure.

DR. ALDERSON: Our next speaker is Dr. Eric Landree from RAND.

DR. LANDREE: Good afternoon. I want to thank you for the opportunity to come here and speak today.

My name is Eric Landree, and I'm an associate engineer with the RAND Corporation.

What I'm going to be talking about today is a discussion of the key findings associated with the RAND workshop that was conducted in October 2005 to look at the policy and planning issues associated

with occupational safety and health for workers exposed to nanomaterials in the work place.

Now, my comments will also touch briefly upon accomplishments of the NII in the particular areas of where they're relevant to the key findings I'm going to discuss. I'll also suggest where in light of the current accomplishments, where additional work may still necessarily need to be done.

A word about the workshop. The workshop was held on October 17th, 2005. The purpose of the workshop was to understand the options available to NIOSH in order to formulate strategic objectives for protecting the safety and health of workers in the work place exposed to nanomaterials.

Now, this meeting brought together a very diverse group of individuals, both government, industry representatives from small and large businesses, industry associations. It also had representatives from the occupational health and safety community who participated as well.

In addition, we sought out and invited participation of labor unions who have an interest in this because of protection for their workers, as well as people from the insurance sector as they're interested in potential liability concerns regarding

nanomaterials and occupational health and safety.

Now, what I've show up here, these are four of the key components of the federal efforts that were discussed as a part of this particular workshop, and I'm going to go through each of these individual four comments.

First, one of the key findings from the workshop is there needs to be greater cooperation between the nanotechnology development and user communities, NIOSH and other relevant agencies engaged with occupational safety and health. For several reasons, this was identified by people at the workshop.

One, large corporations have a lot of information, and a lot of expertise that can be shared with the federal government to help them understand what the potential risks are and provide information to them.

In addition, it was discussed that small firms don't have the same level of access to occupational health and safety expertise [as large corporations], and so by further collaboration and involvement with the development and user community, it will provide opportunities for them to share further information and provide [greater access to] a

level of expertise.

In addition, one of the challenges, as it was discussed earlier, is the need for trying to help identify what areas of research or what type of materials are currently being used and which type of materials are going to be entered into commercial use in the near term.

I should mention that with NIOSH, EPA and other federal agencies through various programs, which have already been discussed by the previous speaker, are making strong inroads trying to engage and work with the user and development communities for nanoscaled materials, which is an important area.

So I'm not going to spend too much more time discussing this first point, but I'll spend a little more time discussing the next three points.

The second point, (which is also identified), is the need to focus federal efforts on critical federal roles: critical federal roles being those activities or those areas that would extend beyond the scope of any individual [corporation] or [beyond the] interest of any individual firm in the private sector.

For example, some of the things that were discussed include understanding the toxicological

properties of broad classes of nanoscale materials, which may, again, extend beyond the interest of any one industry or firm, as well as just testing and developing methods for measuring both dose and exposure for broad classes of materials.

Another important component of this critical, key federal role should also be the ability to provide near term assistance to workers in occupational settings that already are exposed to nanoscaled materials, as well as providing information to other stakeholders as well.

The third point I want to discuss is participants [of the RAND workshop] recommended that federal agencies that develop and implement a unified federal strategy for addressing these critical roles. In fact, the strategy should direct knowledge-based development [to address critical needs] and manage potential occupational risks. This concept would have collaborating federal agencies address key knowledge gaps and provide near term support to protect workers in the work place.

This would also allow federal agencies through this strategic unified strategy to be able to leverage the activities and the expertise of other federal agencies and be able to extend the

availability of existing dollars to address occupational safety and health research.

The fourth point identified by the workshop participants, which I want to bring up is that given the rate of new materials being entered into the workplace and given the current level of investment into nanomaterials for occupational use, as well as the interest in the private sector in developing nanomaterials for commercial use, that the current level of federal investment for occupational health and safe with regards to nano fields should be reexamined.

Now, let me talk just briefly about some of the very important progress and success that has been made by the NII, the NEHI group, in addressing some of these concerns. For example, as discussed in the research needs document, there has been an increase in coordinated activities across the different federal agencies to try and address and coordinate their activities in order to maximize and keep control of or understand what each of the different groups are working on.

In addition, they have articulated some very key research needs that fall under [our description] of critical federal roles, and also they

articulate the next steps that include prioritization, gap analysis and review and updated research needs for the future.

Now, let me go back and discuss briefly a point about critical federal roles. One of the critical federal roles is to conduct research to address uncertainties in nanomaterial toxicology, exposure, dose monitoring, and the effectiveness of exposure controls. These are a sampling of some of the comments that came up during the work shop.

In addition, a critical federal role, as I mentioned, is to be able to protect workers from potential adverse effects associated with nanomaterials in the work place.

Now, I should mention that many of the participants mentioned areas of important critical work that the federal government should focus on and have a critical role that is consistent with many of the research elements produced in the research needs document. I thought that was very encouraging.

However, with regards to protecting workers, an important component of this research strategy and the [NEHI] research agenda is that these [research] findings need to be able to find a way to make their way back to the worker and to the workplace

so that they can be used by workers, and that's a very important part of the strategy.

So I should mention that organizations such as EPA, NIOSH, NIST and others who have close collaborations and work with industry on a regular basis, they have potentially an avenue to help facilitate [transfer of research findings], but this needs to be an area that should be explored.

Now, with regards to the unified federal strategy, we recommend that agencies need to collaborate and collaboratively develop and implement a unified strategy to address gaps in the management of occupational risk. This has several components to it: addressing the critical federal roles, which I've talked about briefly on the previous page; focus on collaboration, not just coordination of activities. Again, this has helped to leverage the existing availability of dollars and efforts across the federal government. Insure that near term needs for workers are being addressed. We mentioned that [during this workshop] discussion there was a comment that there are a large number of federal agencies who are currently conducting research that are pursuing nanomaterials that will eventually be used for commercial products, [or that are] geared towards

commercial use in the future.

And so those federal agencies that have a role and are interested in pursuing nanomaterial research for commercial use have a responsibility similar to industry to make sure that those nanomaterials when they go into industry have been tested and had safety and health related research and risk assessments before they enter the work place.

Now, I should mention -- let me back up.

There are certain areas where the NNI and the NEHI Working Group have made great progress, particularly in the first two points. We're having to insure that, [progress continues and] identify these areas that have critical roles that need to be addressed.

If you'll look at looking at the 2007 description for the supplement to the President's budget, there's a great description of collaborations that currently exist between the different federal agencies, and more can certainly be done.

And finally, I'll be mercifully short. The issue regards resource and funding. Now, the federal government is still the principal driver for nanomaterials research and development and is also responsible to invest in research necessary to protect

the health and safety of workers exposed to nanomaterials.

Now, when this workshop took place in 2005, the estimated budget for environmental health and safety R&D was approximately $38 million or a little bit less than four percent of the total NNI budget.

As of the 2007 NNI supplement to the President's budget, the request for funding for environmental health and safety increased to $41 million, so roughly a 17 percent increase. But if you look at that in contrast to the total investment for NNI, it's about three and a half percent, money that's being devoted toward environmental health and safety research.

Now, what I'm excited about in this morning's discussion was that the definition for what is considered environmental health and safety, there were elements of that that was not included in that original follow-up, which is an important component.

That said, if you look at the amount of nanomaterials that are being directed toward commercial use and that are currently being researched ultimately for commercial use, and you look at the rate at which we're capable of producing information,

needed to help protect workers in the workplace.

The level of federal investment in terms of focusing and devoted to looking at occupational health and safety risks associated with nanomaterials really should still be reexamined.

And with that I'm mercifully short. If people are interested in looking at the conference proceedings associated with this workshop, I have a link here, and I'm happy to take any questions at this time.

DR. ALDERSON: Rick.

DR. CANADY: Hi. Thanks.

Nice presentation. Rick Canady with NEHI Working Group.

You made a point of a need for research to reduce uncertainties with regard to toxicological properties, for example, and exposure and so on. I wonder if you could comment on the unique issues associated with nanotechnology in contrast to what you might do normally for material that's introduced into commerce.

I mean, this is an issue that we keep needing to face, that, you know, you certainly do need to reduce uncertainties for any product that is considered to be, you know, put into the marketplace.

What are the unique nanotechnology aspects of this that you would need to consider?

That's the question I'm facing. I'm not expecting you to answer it in this response, but I wonder if we could get your thoughts on that.

DR. LANDREE: Well, you bring up an excellent point. So in the study of macroscopic materials you have some consistency or in nanoscaled materials, very small changes in composition have dramatic effects on the properties, including toxicity and other effects related to nanomaterials. So as I think was discussed by the previous speaker, how you're going to handle a system that can look at all the possible variations is an extreme challenge.

I think that one of the discussions that had come up and, in fact, I believe was talked about by one of the speakers earlier this morning, is being able to look at broad classes or key characteristics of nanomaterials that are related to toxicity and then use that for developing some sort of predictive capabilities to say, okay, a new material is coming into these characteristics. Can you say something at a first glance about whether this is going to require additional testing of certain sorts? Is that approach?

DR. ALDERSON: Sally.

DR. TINKLE: In looking at the four conclusions reached by the workshop, you focused on occupational safety and health issues. However, has any consideration been given for the potential for population based exposures and broader public health concerns. How would your four points be considered in light of that context?

I see occupational exposure as a subcategory of essentially population based exposures. So could you comment on that?

DR. LANDREE: I will say that when we originally organized and did this workshop, it focused attention on the occupational risks. So what I could comment, I will try and address that but recognize, I think, that it wasn't within the original scope of what we were looking at on this particular work.

But I can say that certainly greater cooperation, EPA which has a role not only in the occupational setting, but also in the global environment, to understand what this is. So certainly their interaction with industry is an important component for the collaboration with industry, which I think influences not only the occupational setting,

but also works outside more generally.

Regarding critical federal roles, using the definition when I talked about in terms of critical federal roles, which are those roles that don't really fall circumspect within a single industry I think is a definition I would apply not only to the occupational setting, but also more generally apply to the environment as well.

I'm working off the cuff here.

DR. TINKLE: But you're doing a great job because I think isn't the point that everything you've pretty much identified for occupational consideration actually does have broader application to public health research. So I guess that was the point, the direction I was trying to ask my question, is that in identifying federal critical roles and a unified strategy, it's not just occupational health. It's a population based exposures.

DR. LANDREE: Yes, and in fact, that's a good point. In talking about the unified federal strategy, of course, it's difficult to talk about nanotechnology, particularly with commercialization and the use of these technologies and commercial products. They're not just staying in the work force.

There have been reports that talk about

employees have potentially the highest exposure rates to nanomaterials because they're exposed to them in the work place. So that is one consideration to take into account when you think about prioritizing research in areas that you're looking at.

But a unified strategy would certainly have implications for areas not only on the inside of the occupational setting, but also outside and more broadly as well.

DR. ALDERSON: Any other questions?

DR. POSTER: Dianne Poster from NIST.

And thank you for the nice presentation.

I was wondering actually on the same slide if you could make a comment on how you mentioned that you would like to see greater cooperation needed between the user and development communities for nanotechnology, and NIOSH and other federal agencies. For example, you mentioned that small firms typically might not have access for resource for environmental health and safety needs.

And how do you envision them making use of, for example, the field surveillance program with NIOSH or also making use of user facilities that are available to these small firms where they can then characterize perhaps their materials with the help of

federal agencies where these national level user facilities are available?

What other avenues do you envision in that area?

DR. LANDREE: I think that's an excellent question, and I think that without trying to avoid the question, I think that we're going to hear later on from people from the Nano Business Alliance, from people who are working with smaller industries. So a way to get access, and [I'd suggest working with these associations] so that I'd be able to approach these smaller corporations or smaller companies that in many cases are producing a lot of the nanoscale materials that are used for commercial products.

An opportunity would be to work with those kinds of organizations, identify them, to try and get a more broad approach, access to these really small corporations who, in fact, don't even realize that the expertise they're looking for is out there in some cases.

DR. POSTER: Thank you.

DR. ALDERSON: Celia.

DR. MERZBACHER: Thank you, Eric.

I heard you say something which I've heard from others this morning. Peter's presentation

included something along these lines, and others have made similar suggestions that there be some responsibility for collecting EHS information in association with the development of new nanomaterials.

I think Peter talked about making a condition of receiving funding be provision of certain information. In fact, you put the onus perhaps on the U.S. government, that the government agencies that fund development work also fund EHS research or something along those lines.

And we all certainly are interested in seeing these research needs addressed as quickly as possible, but I'd like to hear you comment, and maybe I'll talk to Peter off line, about the possible unintended consequence of such a policy that would, because of the sort of big catch-all that is nanotechnology, drive researchers away from calling their research nanotechnology research.

It's putting an unfair burden, you could argue, on nanotechnology research that's not being placed on other chemical development work.

DR. LANDREE: That's an excellent point, and in fact, I've heard similar concerns from people who do research about whether or not something is good nanotechnology or not nanotechnology. So I can echo

that I've heard similar sentiments.

But to echo what was said by the previous presenter, an approach to try and get access to information needs to be multi-faceted and have different aspects, some of which may involve more closely working with the industry trying to get access and directly through programs such as the ones that were discussed here by NIOSH and EPA, regarding trying to get access from other programs. Federal [agencies] funding this research may be another place to get information about that that could not put the pressure on individual researcher, but the program manager for, in fact, collecting some of that information, which I think was also suggested as well.

So I think there are different strategies you can use to try and take perhaps some of the burden off of the organizations responsible for providing that level of information.

Is that helpful?

DR. MERZBACHER: I would argue that then you're going to just transfer the relabeling to the program managers, but yes.

DR. ALDERSON: Does NEHI have any additional comments?

PARTICIPANT: In the process of

exploration and research related to product development, industry has come upon relationships and properties of nanoparticles that have important EHS implications. What do you see is the responsibility, ethical or otherwise, of industry to provide that information in the open literature so that we can avoid pitfalls as a society?

DR. LANDREE: That is an excellent question. Industry by and large has expressed concern about future liabilities regarding nanomaterials that they're working with. I am not aware personally of methods or approaches in which they've tried to address that. My discussion with industry in terms of their concern with nanoscale materials is that they have been very forthright and, I believe -- I'm careful because I don't want to step out of what my area of expertise is.

I'm curious to know whether I have the kind of background in order to answer that question for you, and I think I would be happier carrying the question off line if possible, if that's appropriate.

PARTICIPANT: (Speaking from an unmiked location.)

DR. LANDREE: Yes, it's a challenging question because I don't have enough experience with

industry, particularly large industry, in terms of how they handle and work with nanoscale materials to say what that approach is. Certainly I can see for some considerations they by far have been concerned with liability and the risk associated with nanomaterials. In fact, they're some of the strongest, vocal people about being concerned about the potential occupational safety and risks.

And so I think that they would be forthcoming in that regards if there were risks that were identified. But on that account, I don't know if I can comment any further than that.

DR. ALDERSON: Let me use my discretion and ask you this. Do you have any responses to our questions that the five individuals posed?

DR. LANDREE: No.

DR. ALDERSON: Can't argue with that. Thank you.

(Applause.)

DR. ALDERSON: Our next presentation will be by Mr. Paul Ziegler. He's from PPG, Chairman of Nanotechnology Panel, the American Chemical Council.

MR. ZIEGLER: Good morning. And thank you for inviting me here today and allowing me to speak to such a distinguished group. While I work for PPG

Industries, and that's my day job, I am here to express the Nanotechnology Panel's view and support and effort toward identifying, prioritizing, and coordinating the EHS research for nanomaterials and funding for such research.

In addition to the statement that I will read today, the ACC [Nanotechnology] Panel is preparing detailed written comments, and we'll submit those before January 31st to you folks.

I'm chair of the Nanotechnology Panel of the American Chemistry Council, and I'm pleased to offer the comments today on behalf of the panel which consists of member companies that are engaged in the manufacture, distribution, and/or use of chemicals and have a business interest in the products of nanotechnology.

Panel member companies are strongly committed to developing nanotechnology through responsible product stewardship and sustainable development principles. The panel would like to commend the NNCO for convening this meeting to elicit views on the research needs and the prioritization criteria for the research identified in the nanoscale science and engineering and technology subcommittee document that was entitled "Environment Health and

Safety Research Needs for Engineered Nanoscaled Materials" that was released in September of 2006.

We support and compliment the NSET subcommittee on its document. The identification of research and information needs relating to the understanding and management of potential risks for nanomaterials, it was very comprehensive and very thoughtful. We believe that the document is the foundational document which will be used by the NSET subcommittee and federal agencies participating in the NNI to set and coordinate the priorities for the government funded nanotechnology research programs, including valuable EHS research.

In particular, the panel wishes to support the NSET subcommittee's identification of guiding principles for identifying and prioritizing EHS research, which include prioritizing research based on the value of information, leveraging international and private sector research efforts and using adaptive management for nanomaterial, EH&S research.

The Nanotechnology Panel wholeheartedly concurs that prioritizing research based on the value of information derived from it is critically important.

Additionally, we strongly see the critical

need for federal research related to the environment, health, safety implications of nanotechnology to be commensurate with the growing federal investments in nanotechnology applications and developments.

EHS research projects undertaken by the government agencies, such as EPA and NIOSH, as well as other publicly funded projects, must be coordinated and strategically targeted to achieve the goals set by the NNI. In this regard, the panel acknowledges and applauds the substantial effort of NNI, of what they have devoted to enhancing the coordination across the R&D sector. Federal agencies, as succinctly outlined in the recent National Research Council's review of the NNI, a matter of size, triennial review of the NNI initiative.

We'd like to address several additional points pertinent to the prioritization of EHS research based on a December 2006 ICF International publication entitled "Characterizing the Environmental Health and Safety Implications of Nanotechnology: Where Should the Federal Government Go from Here?"

This report recommends that the EHS research priorities reflect the mix of top down and bottom up priorities forwarded to the NNI by regulatory and research agencies. The panel supports

this type of approach. We believe that it is consistent with the NSET subcommittee's first principle of identifying and prioritizing EHS research, and we encourage federal agencies across the government to take an active, top down strategic review of the EHS research projects forwarded to NNI.

The panel also urges NNI to coordinate strategic research reviews to avoid duplication of efforts and insure that the proposed projects are fully reflective and consistent with the core principles set forth by NSET. In 2006, the panel urged EPA and in its comments on nanotechnology white paper extended external review draft, December 2nd, 2005, to reprioritize its nanotechnology research priorities and to focus research efforts in the following order: chemical identification and characterization in metrology; exposure, fate, and effects; risk assessment; work place practices; manufacturing practices; and green manufacturing and use applications.

These priorities provided a logical structure to maximize the consistency, timeliness and value of the information generated by the research. The panel similarly urges an NNCO to acknowledge that its research hierarchy is consistent with its first

guiding principle for identifying and prioritizing EHS research, and to prioritize EHS research accordingly.

Consistent with the NSET subcommittee's second guiding principle to leverage international and private sector research efforts, the panel believes that NNCO working party on manufacturing nanomaterials for 2007, the working party has identified six specific projects to focus on:

Develop a database on EHS research:

Identify and coordinate EHS research strategies;

Testing of a representative set of manufacturing nanomaterials;

Reviewing and developing test guidelines for testing;

Sharing information on a voluntary and a regulatory program basis;

Sharing information on a risk assessment and exposure measuring.

The timetables being discussed by the WPMN for each of these projects is aggressive, but achievable. The panel encourages the NSET subcommittee to coordinate regularly with OECD, WPMN, and we urge the NNCO to factor that the WPMN schedules into its EHS process of planning.

Finally, the panel urges the NNCO to apply the NSET subcommittee's guiding principles for identifying and prioritizing EHS research and conclude that there is an urgent need for federal funding for the EHS research. The conclusion is entirely consistent with the NSET subcommittee's third guiding principle for identifying and prioritizing EHS research to use adaptive management for nanomaterial, EHS research.

Implicit in this principle is the need to adjust funding levels to reflect the realities of the day. In this regard the panel wishes to bring to the NNCO's attention a letter sent to the members of the House and Senate Appropriations Committee on February 14th, 2006, signed by a diverse group, including large and small companies, non-governmental organizations, and other entities engaged in various aspects of nanotechnology research and development. The letter calls for increased federal funding for nanotechnology EH&S research.

The letter further notes that the federal research is essential to providing the underlying methods and tools critical to developing the fundamental understanding of risk potential of nanomaterials and nanotechnologies, methods and tools

that all producers and users can then use. While reasonable people may disagree on what counts as nanotechnology, EH&S research, for purposes of the quantitative analysis of federal government research dollars, this letter's purpose is entirely consistent with virtually all of the key findings and crosscutting recommendations noted in the documents mentioned above.

It is entirely consistent with the NSET subcommittee's third guiding principle to use adaptive management strategies to insure that we avoid missing opportunities and remain focused on research with the greatest value.

In conclusion, the Nanotechnology Panel supports the NSET Subcommittee's third principle for identifying and prioritizing EHS research. We urge the NNCO to apply these principals as it continues to develop recommendations for future EH&S research priorities and to insure related nanotechnology research is strategically prioritized, coordinated, and funded to achieve the maximum impact within the shortest period of time.

Thank you for this opportunity to make this statement, and I'd be happy to entertain questions.

DR. ALDERSON: Let me start off and ask a question. You talk about developing a research strategy. Could you expand that a little bit in terms of what that would look like?

MR. ZIEGLER: Well, I think a number of the previous speakers and even in what was set forth when you spoke started with characterization definitions. We really need to know what nanotechnology is by definition, what we're dealing with. We need to have well-characterized [materials], what we're dealing with when we have nanomaterials.

Then you need to move to exposure, which a number of people have spoken about. Do we have the appropriate tools to get at the exposure data in the environment, in the work place?

I know that people are working on that particular area. In the risk analysis model, you need exposure. You need to understand hazard. The exposure is a part that is kind of void at the moment unless you have utilized NIOSH, and they have to have several tools to get at what you really have in your work place. It's a void that we have in industry.

We have formed a consortium of industrial members that's looking to develop a prototype of an instrument that would be hand held because that's a

real key in understanding what our hazard risk is in that analysis.

As you move through the research programs within industry, you need to look at what physical-chemical data is important for nanomaterials. It's something that's much more important than when we are dealing with straight organic or inorganic materials. Physical chemistry is extremely important in this nano arena.

And what animal tests or models; what should we be looking at? A lot of what we do is with R&D quantities. You don't have large enough quantities to do even some of the basic toxicology tests at this moment when you've got gram quantities.

So I think you have to move through in a step-wise process. A lot of work is going on, but when you look at what can I grab today and what should I do, where should I spend my dollars when I'm trying to get a product commercialized, it's pretty difficult to grab onto something.

DR. ALDERSON: Rick.

DR. CANADY: You made a comment early on in your presentation about NEHI or NSET performing strategic reviews of research, and it wasn't clear. This is a question of clarification. It wasn't clear

whether you were talking about the research proposals or the finished research or the research in progress. Could you clarify?

MR. ZIEGLER: Well, I think we would probably start with the research. Where do we need research? We've outlined, say, five basic areas, the definition, characterization, exposure that you move through that you'd want research proposals to come forth in those areas and then evaluate their applicability. Are you really going to get out of it what we need to?

I certainly have attended a number of conferences where research data has been presented, and I'm sure it's very good research, and it will be of value some time in the next ten years, but today what I need is [data, results] to help me today on exposure, PPE. Is it effective?

MR. CANADY: Just to push a little bit, I mean, are you seeing something like a study section, like something like an actual review of the proposals as to the applicability to the request?

MR. ZIEGLER: I'm suggesting that at maybe a higher level than it's being done, it's being done within each agency. But at some level these come together and we make sure we don't have duplications

or that we're bringing forth more of what we need.

DR. ALDERSON: Sally.

DR. TINKLE: You represented yourself and correct me if I got this wrong, but through the American Chemical Council that you represent business interests.

MR. ZIEGLER: Yes.

DR. TINKLE: Okay. So we've heard several times today about the need for government to partner with industry or business. So from your perspective, we keep talking about the obstacles to that happening. Do you see that we need to lay a foundation in order to encourage that activity? Is there an openness, given the urgency of the research needs that industry is more willing to partner?

Could you talk a little bit about how you see that from your perspective?

MR. ZIEGLER: Well, I think as a panel we have found the agencies, federal agencies, both here, in North America, as well as in Europe and Asia Pacific where we also participate as individual companies more than willing to open their door and to talk with the panel or with respected members of the panel.

In fact, many of you that sit at these

tables have seen the panel in government offices, in cross-sectional groups of government offices in the same room have seen the panel there. So I would say that we have found the government to be very open in what it is looking for and the panel has also offered to work with and support in any way that we can what's going on.

DR. TINKLE: One quick follow-up. We've also heard in previous talks about the need to stay abreast of the new products that are being developed, the new nanomaterials and industry so that the research is targeted and actionable. What's your opinion from a business perspective on industry providing that information and opening and keeping open that pipeline?

MR. ZIEGLER: Well, I can put my PPG hat on. I can say that we have taken materials from R&D to the first stages of commercialization, which required us to file a PMN, and we had to go to EPA, and while it took longer than we would like because we had to go back and forth, we did get through the process.

So for PPG, we stepped up to the plate and came to EPA under TSCA, which you're required to do when it's new chemistry, new product.

DR. TINKLE: Do you find that a general attitude or specific to your organization?

What I'm looking for is will voluntary regulation, if we invite companies to participate in a voluntary program to disclose materials for research or to engage with government to do EHS research; will we find that willingness to partner broadly in the business community?

I realize there are always exceptions.

MR. ZIEGLER: I don't know if I could categorically for the entire small, medium, and large [companies] in industry say that you're going to get everything you want. I think time will tell whether it would happen.

Certainly any number of companies that I talked to are going to participate in that program or certainly have given indications that they would. I think there are other avenues under the regulatory process if that doesn't appear to be successful that TSCA, EPA has to get at that information, but that's a first step. We have to understand what's there, how they're being used.

What have companies done to get through their current risk analysis that led them to where they said, "We think we can go commercial."

DR. CANADY: Rick Canady with NEHI again.

So within the TSCA framework, much of the information is going to be CBI, confidential business information. Earlier presentations discussed knowledge, databases that look at properties that are generalizable as a way of both organizing the research agenda, but then also as a way of just simply advancing understanding.

Do you have any suggestions about how we might get beyond this compartmentalization of information?

MR. ZIEGLER: That's a very good question, and it's probably a very tough one to answer because of CBI. It's one thing that you file and get a patent on a technology versus we keep it within the company that it is based on technology or how you put things together and you don't get a patent. They're a little tougher to get through.

But I think if you can sit down and plow through it, you might be able to find a way to get a little closer to the optimal world that you'd like to have.

DR. SAYRE: One quick comment on that. Phil Sayre, EPA.

We can use data from confidential

submissions, but mask the actual individual data to develop algorithms for a broader use with new materials that come through. One particular example of that actually is the ECOSAR program to predict adverse effects to fish and daphnia and other aquatic species. So we're already actually doing that.

Paul, do you mind if I just ask one question? I know you've been up there a while.

MR. ZIEGLER: That's okay.

DR. SAYRE: But I was interested in you referring to the ICF and top down and bottom up prioritization. Just who would be the stakeholders in that process?

MR. ZIEGLER: Well, you'd have certainly agency people at the top reviewing these things. The agencies are the ones that are providing the monies currently when you apply for research dollars, and the bottom up is, you know, the researchers, the ideas that they have, and you want to try to get ideas to see whether they fit together.

DR. SAYRE: And does the current structure accomplish that or not quite?

MR. ZIEGLER: I think maybe we're moving closer to something that maybe should have started on day one that you've set out a strategy of what kind of

research we needed; what were the areas of research, and we would have been a little bit more focused on those areas that have bee defined here today of what we need now versus a lot of the research that's probably very good, but when you look at how applicable is it today, in the next one to two years, there are some voids. So there should have been more of maybe a strategy document framework to the research when it all started.

DR. ALDERSON: I have a question regarding the presentation that preceded you, and that's on the issue of the basic versus the applied research, and particularly, I'm asking you because you're representing industry. And if I got this wrong, correct me.

But what I heard the previous presentation, that the federal research agenda should include as part of its portfolio research that supports products rather than developing basic information that would have broad application across many nanomaterials.

I'd like your thoughts on that from an industry perspective.

MR. ZIEGLER: Well, I think that unless it's a common material that you've got multiple

producers of and it's the same chemistry, probably I would say that a product that a company puts into the market has the responsibility to do the evaluation of that product and get it the market safely.

If there are some common things like the nomenclature of the characterization, I think that's something that could be developed across group and say what is really important when we're talking about nano. Is it size? Is it shape? Is it the chemistry?

And these are the points, and that would apply to all of us. That's something that's some basic research because I think it's still being discussed as to what's really the real parameters that are important here. Certainly size in some cases is very important to give you the characteristics. When it comes though to the product itself, you may have a unique product in the market that no one else has. So it should be left at that particular company.

DR. ALDERSON: Any other comments?

(No response.)

DR. ALDERSON: Okay.

MR. ZIEGLER: Okay.

DR. ALDERSON: Thank you.

(Applause.)

DR. MERZBACHER: As Vladimir is coming up,

I just wanted to make an overarching comment based on the remarks we just heard. I'm Celia Merzbacher, I think most of you know, and I'm going to speak with sort of two hats on. One is the co-chair of the NSET Subcommittee and the other is as Assistant Director for Technology R&D at OSTP.

I just want to clarify for everyone in the audience the roles of the different organizations that we're talking about here. This meeting has been organized by the National Nanotechnology Coordination Office, and Clayton is the director. That office provides administrative and technical support. It has a wonderful staff of technical experts and supports the NNI broadly.

One of the organizations it supports is the NSET Subcommittee. That's an interagency group that has responsibility for coordinating this multi-agency activity and for developing plans and strategies that cross over the agencies with representation, of course, from all of them.

But the agencies themselves are the entities that fund the work that goes on. The NNCO doesn't fund the work. The NSET Subcommittee doesn't fund the work. The agencies have that authority, and I just want to make clear in everybody's mind what the

responsibilities and roles are of the different parts of the NNI initiative overall. I think that sometimes there's a little bit of confusion that Clayton has a checkbook with a billion dollars in it, and it's just a matter of coming and asking for some money, but --

DR. TEAGUE: Would that that were the case.

DR. MERZBACHER: These discussions about funding really are very complex ones because the plans that we put out, like this research needs document, are support documents that are taken back to the agencies and used, hopefully successfully, to encourage agencies as they develop their budgets to support the work that's described here.

They're intended to be explanatory, help justify and be compelling in supporting the work that needs to be done. That being said, the agencies that are funding the research have broad missions that includes more than just nanotechnology EHS research, and so they have to take into consideration many other factors in making those kinds of decisions.

So I just wanted to add that to the remarks that have been made earlier.

Thanks.

DR. ALDERSON: Our next speaker is putting

on a different hat. Dr. Vladimir Murashov from NIOSH, but this presentation will be on the International Organization for Standardization.

DR. MURASHOV: Yes. Thank you, Norris, again, and good morning.

Just think of me for the next 25 minutes as a U.S. expert to ISO/TC 229. So in this presentation I will briefly describe to you the standardization needs survey, which was conducted recently by ISO/TC 229.

Just to remind you that International Organization for Standardization develops standards which are based on consensus, that is, view of all interested parties are represented in the development process. The standards are industry wide and voluntary.

The development of standards includes several steps. The first step is the new work item proposal step where a national body would submit a proposal, which is often based on another document developed by either industry or government or non-governmental organization or even another standard development organization. That new work item proposal is voted on, and it requires a majority of voting national member bodies and also at least five national

member bodies commissioned to actively participate in the development of this NWIP for it to go forward.

And at the final approval stage, it is necessary to have at least two-thirds of ISO members who have actively participated in the development of this particular standard and also 75 percent of members that vote for this particular standard to go forward as an ISO standard.

Just a little bit of background about TC 229. As all of you probably know, the Technical Committee 229, nanotechnologies, was established in June 2005. The first meeting took place in November 2005 in London.

At that meeting the working group structure was adopted with three working groups formed. Working Group 1 focuses on terminology and nomenclature and is led by Canada. Working Group 2, meteorology and characterization is led by Japan, and Working Group 3, health, safety, and the environment, is led by the United States of America.

The third plenary meeting of the Technical Committee 229 just took place in December in 2006, in Seoul, Korea, and one of the items which was discussed at that meeting was standardization needs survey. The way that survey was conducted is all national member

bodies were asked to provide the list of potential standards to be developed, and after that, all members were asked to vote.

And the vote took place according to the selection of time scale: immediate development within the next three years, intermediate time scale three to eight years, and more longer term standards to be developed beyond eight years, and according to priority: high priority, medium, low, and not needed.

Every response was given one mark, and then in the end the topic selections from all members were individually totaled.

Then after that, topics were sorted and ordered according to the scores for high priority followed by the time scale. So a total of 233 standardization needs were identified and of those 233 needs, only 111 topics received more than five votes, and five is the minimum number of votes for a new work item proposal to go forward for the development as a potential standard, as I mentioned earlier.

Of those 111 topics, 31 are topics relevant to environmental safety and health, and half of those for immediate development within the next three years and the other half for medium range standard development within the next three to eight

years.

And in the following slides that I will show you, I apologize for the fine print. I have to fit ten potential standards in this slide. I guess I could read them for you.

So the first standard need is the standard method for toxicological screening of nanomaterials; standard method for determining the relative toxicity and hazard potential of nanomaterials; standard guide for controlling occupational exposures to nanomaterials; standard template for material safety data sheet for products containing nanomaterials; nanomaterial product information for use in determining health and safety precautions; standard method for selection of personal protective equipment for use with nanomaterials; standard method for determining the physical hazards of nanomaterials; standard method to establish occupational exposure limits for nanomaterials; standard methods to assess exposure to nanomaterials during consumer products use; and finally, standard methods for determining nanoparticle concentration in air and water.

Again, these are the standards which were identified as the high priority standard which should be developed within the next one to three years, and

they are arranged according to number of votes that they received.

On the next slide you see standards which were suggested for development within the next three to eight years: standard methods for measuring personal exposure to nanomaterials in occupational setting; standard method for performing risk assessment on use of nanomaterials; product safety standards for consumer products containing nanomaterials; standard methods to determine environmental toxicity of nanomaterials; standard method to assess product degradation and the release of nanomaterials from consumer products; standard method to develop nanomaterial product labeling; standard method to assess emissions from handling or machining of nanomaterial containing products; standard method for reporting toxicity of nanomaterials in consumer products; standard methods to determine exposure to nanomaterials in food; methodology to determine effectiveness of filtration media against nanomaterials; standard method of life cycle analysis for consumer products containing nanomaterials; finally, standard test methods for measurement of nanomaterials in manufacturing discharges.

Also, standards in the area of environmental safety and health specifically for nanotubes were identified as high priority standards to be developed, and here you see first standards which were suggested for immediate development, and those include protocol for inhalation testing of nanotubes, for toxicology testing, safe handling, exposure determination in ambient air, exposure determination in water, safe disposal including destruction.

The last three proposed standards are to be developed within the next three to eight years: again, protocols for eco-toxicology testing, for exposure determination in the food, and exposure determination in cosmetics and other skin contact products.

Now, these standard needs, again, could be arranged according to the risk assessment and risk management framework, which was shown on several occasions today. For the purposes of today's meeting, we felt that it would make more sense if we go back to the standards which were suggested for immediate development, [take] a look at them and see what research needs are there to develop these particular standards.

Now, when we conduct that exercise and overlap research needs to develop these standards with research needs identified in the research needs document, the interagency document, we will end up with the following result.

For the area, "instrumentation metrology and analytical methods," these three research needs are essential to develop standards around health safety and the environment of nanomaterials. Those are develop methods for detection of nanomaterials in biological matrices, the environment and the work place; develop methods for standardizing assessment of particle size and size distribution; [and] develop method and standardized tools for assessing nanomaterial shape, structure, and surface area.

In the general research area, "nanomaterials and human health," the following needs are essential for the development of immediate needs standards: Identify [or develop appropriate] in vitro and in vivo assays, models to predict in vivo human responses to nanomaterial exposure; develop methods to quantify and characterize exposure to nanomaterials; and develop methods to quantify and characterize nanomaterials in biological matrices.

In the area of nanomaterials and the

environment, these needs are essential: evaluate testing schemes for ecological effects, understand exposure potential in aquatic systems; develop standardized sampling methods relevant to nanomaterials in the environment.

In the general research area, "health and environmental surveillance," addressing the following research needs are essential for the development of immediate needs standards: understand work place practices and factors that determine exposure to nanomaterials; quantify nanomaterial exposure to the general population from consumer products and industrial processes and products containing nanomaterials; and finally, develop methods for measuring nanomaterial exposures in environmental matrices.

And the last and the biggest research area, risk management methods. There are -- well, we identified six research needs which are essential for the development of immediate needs standards, and those are evaluate the appropriateness and effectiveness of current risk management approaches for identifying those nanomaterials with the greatest potential risk; improve understanding of the unique challenges to process design and engineering control

systems applied to engineered nanomaterials in air; understand efficacies of PPE against nanomaterials as exposure and hazard information evolve; where waste of concern are being produced, determine the best methods for waste disposal; understand factors influencing flammability and reactivity; and finally, understand how a life cycle analysis may be suitable and adaptable to engineered nanomaterials.

And I would like to conclude by acknowledging the help of Chairman of the Technical Committee 229 on Nanotechnologies, Dr. Peter Hatto, and Mr. Steve Brown with Intel, who is the convener of the Working Group 3 on health, safety, and the environment in the development of the slides and also who were instrumental in conducting the standardization needs survey.

I also would like to thank the ISO Technical Committee 229, Working Group 3, national and international experts for their time and commitment to this process.

And thank you for your attention.

(Applause.)

DR. ALDERSON: Any questions for Vladimir? Rick.

DR. CANADY: Rick Canada, NEHI Working

Group and Food and Drug Administration.

In the OECD meetings that have been going on over the last couple of years, we've talked frequently about coordination with ISO, between OECD and ISO. I wonder if you could speak to that, and particularly with regard to some of the test methodologies for aquatic ecosystems, human health effects and so on that were mentioned as research needs or actually standard methods that would be developed under ISO.

Are you talking about development of test guidelines, in effect?

DR. MURASHOV: Well, my understanding --

DR. CANADY: Maybe an easier question to answer would be, you know, is coordination with OECD and other internationals being considered in any formal way.

DR. MURASHOV: Right. Well, I can tell you that presently there is a formal liaison between the two organizations, that is, representatives from ISO/TC 229 participate in the OECD Working Party on Nanotechnology meetings and vice versa. So there is at least an exchange of information at the formal level.

Also, as I understand there is an

agreement -- well, I don't know if it's formal or not formal -- if one body develops a standard, it will be used at least as an input by another body, so to avoid repetition. For example, as I understand, OECD is looking up to ISO to develop nomenclature standards at the moment.

I don't know if Clayton, who is the chair of the technical advisory group for ISO/TC 229 could [provide further comments].

DR. TEAGUE: Just to briefly answer so that it's clear for the rest of the audience here, there is underway at least plans and initial procedures to set up fairly formal liaison relationships between the ISO Technical Committee and the OECD Working Party. I don't think there's anything been decided at this point, but I know that it's actually underway. Maybe Jim will say something about that a little bit later today when he speaks, but it is underway.

DR. ALDERSON: Sally.

DR. TINKLE: I don't know much about the ISO process. So could you explain to me? Now that ISO is identifying standard methods that need to be developed for all of these many areas, how does ISO implement a process to get the standard methods

developed? How do you apply the plan that you've developed?

DR. MURASHOV: Right. Okay. So the hope is that once these research needs were identified, it would act as a stimulus to national member bodies for them to put forward new work item proposals. That is, they would know that these are the areas where they can expect that at least five other members would be actively participating in developing these standards.

So there's no real formal mechanism which would force, if you wish, member bodies to develop specific standards identified. You know, this survey is more of an encouragement.

DR. ALDERSON: Phil.

DR. SAYRE: Vladimir, thanks. It was a really informative presentation.

I just had one specific question. On one of your slides for nanomaterials in the environment, it calls out specifically understanding exposure potential in aquatic systems. What was the rational behind that as opposed to other environmental media?

DR. MURASHOV: Right. I'm afraid I won't --

DR. SAYRE: Or is that simply part of the voting process.

DR. MURASHOV: Right, yeah. You just have to remember the way the list of standards needs was developed is by contribution from individual national member bodies, and then there was a vote. So it would be difficult for me unless I put that item on the list; it would be difficult for me to say why it was chosen.

DR. SAYRE: So ISO doesn't provide any particular justification --

DR. MURASHOV: No.

DR. SAYRE: -- for any of these

DR. MURASHOV: No.

DR. SAYRE: Okay. Thanks.

DR. ALDERSON: Any other questions?

MS. GEROULD: This is Sarah Gerould from USGS. I'm on the NEHI Working Group.

First, a clarification question. You had a number of time frames there, five years, three to eight years, whatever, and could you clarify what you meant by those? Is that the time frame from today or is that the time frame once you have the information, the fundamental research information that you need in order to actually develop a standard?

DR. MURASHOV: My understanding is it's from today. The time scales are from today, yes.

MS. GEROULD: Today, and this is a more philosophical question. How do you know that you have the basic information that is needed? At what point can you say, "Okay. Now, I have enough information and I can develop a standard"?

And if you find out later you don't have all the information you needed, is there any mechanism to go back and say, "We need to revise this standard"?

DR. MURASHOV: Right. There's no mechanism to -- well, at least it wasn't done through ISO through this survey to assess whether there is enough information to develop this particular standard. So it will go back, I guess, to individual national member bodies, for them to see whether there is enough information to develop particular standard. So that's the first part of your question.

The second part of your question is whether there is a mechanism for periodic assessment, and evaluation of the standards. Yes, ISO does have that mechanism, and you can see more on ISO Web site on that.

DR. TEAGUE: Let me just add a few comments to that. I mean, to give you some perspective on the scope of ISO for those of you who might not be familiar, in this particular technical

committee, there are 28 nations now that are participating as members of this particular technical committee.

So it has broad international input from totally across the world. The other one is that don't be anxious about there being standards formulated without firm information. Most of the standards are developed based upon very, very solid things are in place. You don't standardize things which are in a research status. Almost always if you're standardizing how to measure the diameter of a nanotube with a scanning electromicroscope, you know everything about how the electron beam interacts with the nanotube and how to measure from the profile exactly what you're going to declare as the edge points and things of that nature.

So standards are based upon very solid information which is operational, been put in practice, and has been examined by experts literally across the world before things move forward, and if there's any questions, they're typically addressed very, very thoroughly before it's finally approved.

DR. ALDERSON: Well, this concludes this morning's presentations. For lunch there is a cafeteria that I hope you saw when you came in

downstairs or you can go any other place you want. It is up to you.

We will start promptly back at 1:30, beginning with Dr. Andrew Maynard for his presentation.

So thank you all, again, for being here, and we appreciate your input.

(Whereupon, at 12:12 p.m., the meeting was recessed for lunch, to reconvene at 1:30 p.m., the same day.)

AFTERNOON SESSION

(1:32 p.m.)

DR. ALDERSON: Well, by my watch it is 1:30. So we will get started.

DR. MAYNARD: Thank you. Seventeen years ago, scientists published some of the first nanotechnology risk research findings suggesting that nanometer-scale particles behave differently compared with larger particles in the lungs. Fifteen years ago, the first concerns were raised about the potential health impacts of using carbon nanotubes in commercial products. Thirteen years ago it was becoming increasingly clear that the impact of some nanoparticles is dependent on, not the usually measured mass concentration of material inhaled, but other properties such as the size and the surface of the particles. Coming close to the present time, three years ago the Royal Society in the UK and the Royal Academy of Engineering published a fairly comprehensive set of recommendations on what needs to be done if we're going to insure the safety of emerging nanotechnologies.

And here we are the beginning of 2007 with what I think is the first public meeting addressing research prioritization in this area. Glad to see

we're moving fast on this one.

What I want to do because I have fairly limited time and because there is already a lot of information out there on what needs to be done and what the priorities are, I want to focus on three very simple but very specific points which hopefully will help focus attention on some of the things that need to be done and some of the priorities here.

Let me see if I can get this to work. Oops, that's interesting. Well, it looks like I'm going to be giving a blank -- oh, no, it has come.

The first point I want to make is very, very simple and that's risk research has a purpose. This may seem to be blindingly obvious to everybody in this room, but I don't think it always is that obvious when we're looking at the research portfolio and we're trying to prioritize research.

And, of course, this purpose is to insure the health and the safety of not only us, but also the environment in which we live. The danger of forgetting this is we end up investing millions of dollars in exploratory research and then only after the fact trying to work out how we can apply that research to understanding and addressing risk.

This is a little bit of the wrong way

around, if you like, for some of the specific questions we have to answer. Let me just give you a very quick example. I have here a NIOSH certified N95in disposable respirator. Now, this is a respirator which is tested with 300 nanometer diameter particles.

But what happens if NIOSH wants to know how effective it is for, say, ten nanometer diameter particles? It seems like there are two choices. Either they can distribute millions of dollars into the research community. That's assuming hypothetically they have millions of dollars. Cross their fingers and hope somebody comes up with the right answer. That's exploratory research.

Or they can actually go to somebody with the expertise and ask them the specific question: test this respirator with ten nanometer diameter particles.

The point is there are some cases where we have to ask specific questions and they have to be related to the questions we want answering. We have to remember that risk research ultimately has a purpose.

The second point, very obvious point I want to make is that prioritizing risk research is not

rocket science. It's sometimes easy to become overawed with the complexity of the problems that we face. In fact, if I put up a quote from the director of the National Science Foundation at one of last year's House Science Committee hearings, let me just read this out to you. This says from Arden Bement, last September.

"I have to tell you that this area is so complex that I don't know of any person or a small group of people who would be smart enough to be able to identify all the risks, set priorities and lay out a so-called game plan."

Well, let's just think about that. The impression seems to be that this area is so complex we cannot make any movement at all. Yet I'm not sure I agree with that, and again, let me use a second example to demonstrate that.

Let me show you a product which is already out there on the market. This is an alleged nanotechnology product, nano calcium and magnesium dietary supplement, Dr. Gunderson's proprietary formula, no less.

Now, let's just have a look at this and see how it helps inform us on the sort of priorities that we need to have. So I have this. I open it up.

I find it's a fine powder in there. In fact, some of you close to me will see the powder coming up into the air. In fact, I can actually smell the powder. Now, let's see how we use this.

Okay. Directions for use. Add one teaspoon full of nano calcium magnesium powder into water or tea. Well, you may not be surprised to know I have -- I did have a cup here with some water. It's not as warm as it should be, but it will certainly do the trick.

So if I was using this product, I'd pour myself a cup of water, get my teaspoon out. I always carry with me. Here we have the product. It's easy to spill so I'm probably getting some on my skin in the water.

So this is my nanoproduct which I'm now using. Now, I guess the directions are to drink it. Cheers.

Well, actually I'm not going to drink it because I don't actually like magnesium. So I'm just going to leave it there. But just think through those actions. What I did, I opened this up. Some stuff was released into the air. Was I exposed? How much did I breathe in? What did it do in my lungs? How would I measure that?

I got some on my skin. Is that going to penetrate through my skin? Is that a question we need to address?

If I would have drunk this, what happens to this stuff in my body? This is a fairly opaque mixture here. Clearly, fine particles are still set in suspension. What does it do in my guts?

When I eventually pour this down the drain, what is this stuff going to do when it hits the environment?

Okay. Granted there are some complex questions associated with prioritization, but when you look at some of the specific products, some of that complexity disappears and there are a fairly clear set of priority questions that need to be addressed if we're going to understand how safe and potentially how dangerous some of these materials and products are.

My third and final point is that risk research needs a plan. We're here to talk about research needs and research priorities, and I would say that's an essential activity, but you can't do that in isolation. It has got to be carried out in the context of a strategy, a strategic plan.

If you're going to effectively look at nanotechnology and the risks and how to manage those

risks, you've got to understand three things. You've got to understand where we are now. You've got to identify where we want to be, and you've got to identify how you're going to get there. Three essential components of a strategy or a strategic plan.

And what I want to do in the last few minutes that I have is just highlight one or two resources which I think can help in this process of developing such a strategy. These are specific to the project of emerging nanotechnologies. In many ways they complement the other resources that we've already heard about today and will hear about later.

The first two resources I want to put up address where we are now. This is, of course, essential. If you're going to have a strategic plan, you need to know where you are in order to get to where you want to be, and there are two resources here which I want to draw your attention to.

The first is the project on emerging nanotechnologies inventory on consumer products allegedly based on nanotechnology. This is a publicly accessible inventory on the Internet. We have nearly 400 products listed in this inventory. It is not comprehensive. I know there are some products in

there which are not nanotechnology as many people would define it, but it is as far as we're aware the most comprehensive source of information on the types of nanotechnologies that people are being exposed to as we're sitting here in this room.

This I think is a very valuable starting point for understanding how nanotechnology is entering society now.

The second resource, which I want to highlight, is the project on emerging nanotechnologies' inventory of risk research. It has already been mentioned at this meeting, I believe, that we need to understand what research is going on. In fact, I saw, Norris, from your recent comments following the House Science Committee that you acknowledge that we need an inventory of current research if we want to now what is going on now and what we need to do to fill the gaps.

Well, I'm pleased to say that this inventory exists on the project of emerging nanotechnologies Web site, in fact, has existed for the last 12 months, and I would encourage you to use this as a resource.

Now, let me just say a couple of things about this because I think there has been a little bit

of confusion over the last 12 months on the applicability and usefulness of this inventory. What we have here is a listing of all the publicly available information and current research which may be relevant to understanding the risks of engineered nanomaterials.

And I put that "may" there very specifically because we've had a very, very broad selection criteria for this database. We've included research on incidental nanoparticles. We've included research on applications which might be relevant to implications.

The trick, however, is that we've allowed filters on this. So other people can come along and identify the research which is relevant to their needs. So you can go into this database. You can carry out the research on research which is either highly relevant to understanding risk, marginally relevant or having some relevance.

In addition to that, you can carry out an investigation into research which is either specifically focused on engineered nanomaterials or research which is focused on other types of nanomaterials which may nevertheless inform our understanding of engineered nanomaterials.

By putting this inventory together in this way, we have effectively created a resource that other people can use using their criteria for identifying what is important to them, and by "them" I'm referring to people who want to look at developing a research strategy. I'm referring to groups who want to develop partnerships with other people that have got similar interests in doing similar research.

The third resource that I want to mention goes into the future, and to a certain extent looks at where we want to be, and this is the recently published paper in Nature, "Safe Handling of Nanotechnology." This is a paper co-authored by 14 international scientists who got together and try to identify what the five key challenges are to understanding the risks associated with nanotechnology, essentially identifying where we want to be over the next five, ten, 15 years if were going to see responsible safe nanotechnologies developed.

And I would strongly urge you to look at this in terms of identifying and informing some of your prioritization. This paper is not a strategy. It is not necessarily a prioritization, but it presents pillars on which you can build an effective strategy, I believe.

The final resource which I want to list is the Project on Emerging Nanotechnologies' report which came out last year, looking. Looking at a research strategy for addressing nanotechnology, environmental safety and health.

This is a report which did a couple of things. First of all, it identified some of the more immediate research needs, research needs which really have to be addressed over the next two years. But it also began to develop a framework for prioritizing that research and identifying what needs to be done now as opposed to what we can maybe put off for two or three years.

And, again, I would strongly recommend that you look at some of the recommendations in this report for prioritizing research.

Now, this is a report which I would consider begins to develop an idea of how we get to where we want to be and looks at mechanisms for pushing forward a strategic research plan, and in that respect it has a number of recommendations.

One of the things that it does address, which is critically important here, is who is going to pay for the research. Important because no matter how much you develop lists of what needs to be done, no

matter how much you talk about prioritizing these lists, if you consider this research to be vital, somebody has got to pay for it; somebody has got to take responsibility for it. You can't ignore that fact.

So those are the resources I wanted to call to your attention. I just want to finish off by coming back to my original point, and that is that risk research has a purpose, and that purpose is to protect people like us and the environment from harm. I think in the absence of anything else, this is a very, very useful guiding principle for looking at current research and potential research and beginning to decide what is important now, what is important maybe in the future, and maybe what isn't so important.

So 17 years later from some of those first reports looking at the potential health impacts of engineered nanomaterials and ambient nanomaterials, we are now in the position where we have enough information to be able to craft fairly sophisticated questions on what needs to be done and when it needs to be done.

The next step I believe is to move very, very rapidly in developing appropriate strategies and

starting to fund and enact research which is going to lead to clear results and applicable results.

Thank you.

(Applause.)

DR. ALDERSON: Clayton.

DR. TEAGUE: Andrew, I've read over your Nature paper and the ones by the group of experts that you had pulled together, and when I look it over, it looks, like there's a lot of very, very high similarity between what's identified in the Nature paper and the five research areas identified in our document.

What's your reaction? How did you see that similarity or differences?

DR. MAYNARD: No, I think you're right, and earlier this morning, as the people in front were going through those areas, I was actually ticking off where the similarities are.

It's perhaps not surprising because people have been talking about these areas for some time now. There was a very, very close level of agreement. I think, in all areas apart from one, we had very, very close coordination between the challenges we put out and your areas.

The area that we didn't hit on was the

area of surveillance for a number of reasons, and that's probably the area if you look at the NEHI report I probably have the most trouble with, with parts of it, not with all of it, but certainly that's one of the areas where there are fairly complex questions which I think need to be fleshed out in more detail.

DR. ALDERSON: Sally.

DR. TINKLE: Andrew, I have a question about the rate at which one can achieve research. Given the talk earlier this morning on the instrumentation and metrology needs, how do you view those needs in light of moving forward in risk analysis? It seems to me that there is a bit of a disconnect there. So perhaps you could address that and your thoughts.

DR. MAYNARD: I think you're right, and I think there's a very real trap of trying to carry out quantitative research here in a linear fashion. If you try and do that, you'll never get to the end of the tunnel because you're right. A lot of stuff follows on from understanding how you characterize and measure these materials, and yet we're not going to have definitive answer for another five-plus years in that area.

The only solution as far as I can see it is to be very pragmatic and take small steps towards what we can do immediately while planning for the future in developing more robust strategies for future research.

So, for instance, in terms of instrumentation, what we can do over the next two years is we can devise relatively simple instruments for measuring exposure to, say, to particle surface area, particle number concentration, particle mass concentration, which will begin to give us insight into what people are being exposed to and how to control that exposure.

Now looking to the future we can begin to develop more sophisticated measurement methods which will then tie into some of the biology which is developed.

So I think that the solution is to have multiple tracks and identify short term aims as well as long term goals.

DR. TINKLE: Can I ask one more?

DR. ALDERSON: Sure.

DR. TINKLE: One more follow-up on that. Oh, I just lost my question.

DR. ALDERSON: Rick.

DR. TINKLE: Thanks, Rick.

DR. CANADY: Sure. I'm not going to ask your question. I might ask another one.

Andrew, in your example with the magnesium supplement, the thing that I kept running through in my brain was what if that was a micro sized supplement. What questions would you ask differently? What approach would you ask differently?

And I think it also gets to the intro to that example, Dr. Bement's quote. I think he was talking about the broad class of nanomaterials, and in a sense you were talking about looking at an individual product and evaluating it on a product by product basis.

I realize there's two questions here.

DR. MAYNARD: There are two questions there, yes. Let me try and remember both of them and answer them.

First of all, asking a question what if this was a micron scale rather than a nanoscale material. If you're interested in the potential health impact, I think you've still got to ask questions like that. You can't be so dichotomous that you say nano is harmful or nano is not. At the end of the day, we're interested in protecting people and

protecting the environment.

The reason I would specifically be concerned about the nanoscale is because we have evidence that below a certain size, whether it's 100, 200, 300 nanometers, particles begin to behave differently in the body. So that would be my trigger, beginning to ask specific questions like this.

Now, going to Arden Bement's quote, and I was playing around there with it obviously because if you look at the whole scope of questions that need to be addressed, there are some very, very complex questions out there that are going to need exploratory research so that we know how to frame the questions.

At the same time, in a prioritization context, there are some very, very immediate and very specific questions, such as what does material like this do, which have to be addressed.

So my point obviously was there are complexities there. There are some questions which can be prioritized relatively simply.

DR. ALDERSON: Phil.

DR. SAYRE: Andrew, you pointed out that probably one of the more relevant documents that's a parallel to the EHS document we're presenting today is the one that you authored fairly recently. With that

in mind, could you quickly summarize if it's possible, for instance, the chart of many colors is impossible, but could you quickly summarize, for instance, what you have for the most immediate research needs?

And also, since we're interested in how to prioritize and criteria, could you mention some of the criteria?

DR. MAYNARD: I don't have the document in front of me. So I --

DR. SAYRE: I'm happy to loan you my copy, except I'll have to have it back for a follow-up.

DR. MAYNARD: Well, okay. I probably don't need to look at that that much.

First of all, in terms of the priorities, in fact, let me just hold this up. This multi-colored chart here which will be meaningless to anybody more than about two foot away from this, but the reason I put it up is to emphasize that I came to the conclusion when I was looking at research priorities you've got to have parallel tracks. You can't do things in a serial fashion, which means what you see here, you have multiple research priorities which are being worked on at the same time, but you've also got research priorities which have been identified as being important five, ten years from now, and yet we

need to start investing now in some fairly basic research if we're going to be able to address those in the future.

So that's where the complexity of this comes from.

Now, before you come back to me, you asked me what are some of the big challenges in the future. My contention here was looking in the short term over the next two years, we've really got to focus on specific issues of what is either close to market or in the marketplace at the moment. Essentially, what are people going to be exposed to? What's going to be released into the environment?

And that means key issues come up, such as how do you measure exposure in a fairly pragmatic way, not looking at how you apply the latest multi-million dollar electron microscope to characterization, but how you develop a cheap, effective instrument for getting at least an idea of what exposure is.

How do you evaluate toxicity, specifically looking at toxicity screening tests as opposed to predictive toxicology? How do you control releases of nanomaterials both as you're using them in the work place, also as you're putting them into products which are entering the environment? And how do you develop

safe and effective ways of working with such materials?

These are all points which I think have come up from previous presentations. In fact, many of these are points which came up in the NEHI document, and if you look at Rick's section on risk management, a lot of these are points which were highlighted in that particular section, I think.

DR. SAYRE: I think the complexity of the diagram you have there indicates that this is not exactly a straightforward process. You have very short term research goals and then you have another category that refers to beginning early on medium term research goals, and then you have -- I forget the language because I don't have the document -- but longer term research goals.

DR. MAYNARD: Right, yes.

DR. SAYRE: So, essentially you have, as I said, a very complex picture of how this whole thing should move forward.

DR. MAYNARD: It is complex, but it's not that complex. I'm a scientist. Many people here are scientists. We deal with complex issues, and in terms of some of the science we do, this is not complex. This is maybe difficult, but not complex.

DR. SAYRE: It's a lot to budget, I guess is what I would say.

DR. ALDERSON: Vladimir.

DR. MURASHOV: Andrew, since you mention that there are some differences between the Nature paper and NEHI research needs document in the area of surveillance, can you please be more specific?

DR. MAYNARD: Yes. The whole area of surveillance is difficult, and depends on how you interpret that word "surveillance," but it's difficult because in essence if you're not careful you're beginning to take measurements, test people, ask for any personal information from people when you don't exactly know what you are looking for, and that has fairly profound ethical implications.

And so when I was looking at what was up there, some of the stuff was clearly very appropriate, but other areas I think we need to be a little bit careful in deciding that we have to go out there and do a lot of surveillance, ask a lot of personal questions if we don't know what we're looking for.

DR. ALDERSON: So did you get your memory?

DR. TINKLE: I got my memory back. What I wanted to look at a little more closely was this is a second major emphasis on risk management driving the

research prioritization and the research strategy. Yet in answering questions you talk about exploratory research. So clearly, that's a component of what you're thinking about and a melding of the two.

DR. MAYNARD: Yes.

DR. TINKLE: So what kinds of proportions? How are you going to reconcile that? Because your slides came pretty forcibly down on the side of risk driven science. So --

DR. MAYNARD: The short answer is it depends how deep the pot is.

DR. TINKLE: Okay.

DR. MAYNARD: If you have a little bit of money --

DR. TINKLE: And the long answer?

DR. MAYNARD: -- you have a big problem. Well, if you have a little bit of money and you have a big problem, you've got to put the money where the immediate issues are, and that brings you to what I would call the targeted research.

Ideally, you want to be investing in exploratory research as well, and that's where you need substantial increases in budgets, as well as a clear focus within a strategic program as to what sort of exploratory research is going to be useful and how

you use the results of that research.

DR. TINKLE: But given the questions we have about how to measure dose, instrumentation to measure dose correctly, how are we going to go out and ask those targeted questions solely in a risk management way?

DR. MAYNARD: Right.

DR. TINKLE: I'm really grappling here with how we're going to do this.

DR. MAYNARD: And it is not easy, and this is precisely why you've got to have these feedback loops, because we definitely won't get it right first time round. But I think we can't afford to do nothing until we feel we understand where we're going. We've got to make some sort of progress.

So, for instance, if you're looking at exposure metrics, for instance, we've already got enough research to tell us that the surface area and surface chemistry are probably important, but also in some cases mass and number concentration are going to be important.

We have ways of measuring those. They're not particularly good, but we do have ways. We can actually make a start there. We can refine our methods of measurement fairly rapidly, and then as we

begin to feed that into some of the more exploratory research and maybe other things come up, we can begin to iterate around and revise those approaches.

DR. TINKLE: So I would argue that it is complex, but we can make progress.

DR. MAYNARD: I would go with that.

DR. TINKLE: All right.

DR. MERZBACHER: Thanks, Andrew.

I'd just like to get back to the questions that we posed at the front. I don't know if this is the last question you'll get, but just sort of as a reminder, the principles by which we identified that we would prioritize the research needs that are shown in the document are the extent to which information will reduce uncertainty, the extent to which information could be used broadly, the expected use of material -- are they going to be used in a lot of things or just a few, the exposure potential of a particular material, and the availability of other data that could be leveraged. Then also we call out wanting to work with international and private sector partners and be adaptive.

So that's just sort of a quick summary of our principles. You've gone through some kind of prioritization exercise yourself in the Nature

article, for example, and in the report that came out last summer. Did you use any criteria in addition to these?

DR. MAYNARD: You know, I can't think of any that we used in addition to those. Many of the criteria were very similar to those. I think there were possibly one or two areas of departure.

But, of course, what I would say is that that's a fairly generic set of criteria. I think to be fully effective, they're really got to be further developed so that you can see very clearly how to apply them to research.

And I have no problems with that list. I think it's a very good starting point, but I think it probably would be useful to refine it further and see how it specifically applies to specific research areas.

DR. MERZBACHER: Well, we would welcome your written comments between now and the end of the month.

DR. MAYNARD: I'll see what I can do.

DR. ALDERSON: I have one question and we'll wind this up, Andrew, and that's in relation to your database. In my comments this morning, I talk about an inventory that we're going to be getting

through OMB of what the agencies are funding in 2006 using what's in the document to categorize research.

Would you expand on how you recommend we use your database or in place of that or in addition to?

DR. MAYNARD: I would actually recommend that you use our database in addition to that. I think if you look at the role of government here, you've got to have accountability in terms of the research that's being conducted, and that's where you need the specific sort of exercise with OMB.

But I don't think that that will give you the information that you need to inform a strategic research plan. I say that specifically because there are complexities here, and people sitting up here on stage have already alluded to this, that you're going to have some research which is looking at an application of nanotechnology but which is also as yet going to be relevant to understanding the implications.

Now, it's very, very hard to capture that research if you just have a set definition of what is to be included, what is not to be included. What we strive to do in our database is to have a fairly flexible set of definitions so that somebody else can

actually go in and apply appropriate filters and pull out the information they need.

So from that respect alone, I think I can see a very, very complementary use of our database complementing the information that would come out of OMB.

DR. ALDERSON: Good. Thank you.

DR. MAYNARD: Thank you.

(Applause.)

DR. ALDERSON: Our next speaker is Dr. Bettye Maddux, [Oregon Nanoscience and Microtechnologies Institute], Safer Nanomaterials and Nano Manufacturing Initiative.

DR. MADDUX: I was wondering how I was going to give my talk without slides.

First of all, I'd like to thank the Nanotechnology Coordination Office for giving me the opportunity to speak today. It's a privilege, and we feel it's very important to have this meeting.

And I'm happy to speak on behalf of the Oregon Nanoscience and Microtechnologies Institute of which the Safer Nanomaterials and Nanomanufacturing Initiative -- which because it's a long phrase I'm going to call SNNI -- is one of the major research thrusts.

So with that said, I think we can all agree that the properties at the nanoscale offer opportunities as well as uncertainties. The basic question then is, "How do we maximize the opportunities that nanoproperties [and] nanomaterials will give us, [but] minimize the uncertainties?"

A general consensus, I think, that has come from this meeting, is that nanotechnology has the power to revolutionize our society. It's a technology that's coming, but we also need to understand the risks as well as the benefits. We need to understand the uncertainties [surrounding nanomaterials and their real effects]. We need data for that, and I would also add the caveat that public perception in this case matters. That has been shown through, at least locally through, issues of the past [GMOs], and that one of the important aspects of this [perception] is that we need to educate the public and keep them informed of our progress so that we don't repeat the mistakes of the past.

So I'm just going to delve right into what I think SNNI's research priorities and needs are. We're interested in taking a proactive approach to nanomaterial design, and this is just a simple outline of some of our needs, and what we think the needs are

with the industry as a whole.

I'm going to get into this [more] as I go along in my talk. What do I mean by a proactive design strategy? Basically that's to design materials that provide new properties that are high performance, but pose minimal harm to human health and the environment. [We need] to be able to scale up that [production using] those design principles into manufacturing quantities while also minimizing hazardous substances, to try to minimize the risks or minimize the harm. Then we can be able to apply these nanoparticles or nanomaterials for device applications.

The basic idea is an iterative process where we use green chemistry to synthesize nanomaterials, test for environmental and biological impacts, redesign if they are shown to be toxic, [repeat] until we get it right. The idea is that we have high performance materials that are cheaper and greener and hopefully not as toxic.

So then the idea behind green nanoscience would be merging green chemistry and nanoscience to produce safer nanomaterials and more efficient manufacturing processes. So the idea is to move from basic research to applied research, to be able to take

our design schemes and scale them up to production level quantities.

With that said, I'll give you a brief introduction to SNNI. We have three research groups that are composed of about 25 faculty members from Oregon State University, the University of Oregon, Portland State University, and Pacific Northwest National Lab. It's a very multi-disciplinary, multi-university group, and we have three research themes that we feel are important to move the technology forward.

The first group studies the design of nanoparticles to where we can control the size and the shape of the [nanoparticle] core, the stabilizing shell and surface functionalization groups on the nanoparticles, to very precisely fine tune the nanoparticles for use in nanodevices. Then we have a group of toxicologists who will take those [nanoparticles] and then test them in biological systems. Then our engineers will take the synthetic methods for preparing the particles [and incorporate them] into nanomanufacturing devices so that we can have scalable quantities of nanoparticles with widely tunable properties to them for making nanoscale devices.

And that's basically SNNI in a nutshell. [The next slide will] give you a brief example of some of the toxicity testing that we're doing. We're taking a tiered approach to use toxicity screening, both in vitro and in vivo; we are also assaying for cellular targets of distribution within the animal defined in vivo, and also looking at molecular expression.

We also have a toxicologist on board who is interested in developing a nanomaterials effects database. This would be a database that is all-encompassing, that would take all of the known available data on nanoparticles or nanomaterials, and put it into an integrated database that is searchable so that you could find out anything you wanted about this particular class of nanoparticles, [search for] the toxicity testing, environmental hazards, be able to model, use the data from that for modeling in the other studies. The idea is to develop the database first so that we can fill it in with data as it comes down the pike.

And now I'll just get into some research strategies and needs assessments that we've recently put up on our web site here at greennano.org that outlines what we feel are the research needs and a

prioritization of them. And this [slide] is an outline of what I'm going to be talking about, and I will go into a little bit more detail on these.

Essentially we need to take precautions in the face of uncertainty. Another prioritization would be use using the proactive design schemes. That means designing nanomaterials for safety.

Just to take them one step at a time, there's a first level risk assessment where the questions that we would ask are, can we examine the properties of our nanomaterials using current knowledge of molecular and microscale analogues? Can we compare the hazards as a first step?

Another we would add is that we want to be able to understand the elemental composition and putative effects of [nanoparticles on the elemental level]. So, say we're working with gold nanoparticles and gold is considered biocompatible. Do we really know what happens with the elemental [level]? What if any degradation happens in the environment or in the body?

What is the dispersal [pattern]? Is it going to be toxic? What kind of accumulations?

These are all important questions that we feel that need to be answered on the first level of

risk assessment.

Precautions in the face of uncertainty. If there is no available data on the hazards currently, how do we currently measure exposures? And that was brought up in the last talk, very nicely, that we do need testing schemes for consumer products that are available. But the questions that we have need well-developed assays for testing them. Who is going to develop those assays and who will be the judges to determine the quality of those assays?

Designed for safety, fact finding. This basically means we need to develop tests to ascertain the impacts of nanoparticles on health and in the environment, and in order to do that, [this should be] included in the biological testing. We need standardization [methods] of how these will be analyzed. So if we're going to have this database where we want to be able to compare the data [from toxicity tests], we need to be able to compare them [based on experimental design]. So we need to be able to understand, be able to compare based on concentration, for example, or surface charge.

So it would be really nice, I think, as well as important, to be able, especially with toxicity data, to be able to compare it amongst all of

the variety of diverse groups that will be doing these studies.

We need well-characterized nanomaterials with respect to course composition, size, and shape, pure synthetic libraries for biological and environmental testing. We can test commercially available as well, an important assay to do, but we must understand the effects of impurities on the commercially available [nanoparticles] because impurities can sometimes mask the total effects of the nanomaterials that happens within a system.

We also need to be able to share our data in order to determine the risks and the benefits. So, the data needs to be managed to facilitate, for example, the structure activity relationships.

Another aspect of design for safety would be to develop synthetic strategies. If we want to use green chemistry to make nanomaterials and nanoparticles, to minimize the harm and [maximize] the benefits in the beginning, then we will need to develop nanoparticle fabrication processes that control the properties of the nanoparticle using green chemical methods.

At SNNI, we are currently in the process of developing some of these fabrication processes

using green chemistry methods. If we want to be able to purify them, we need new methods to assess the purity of them, as well as new purification assays, for example, nanofiltration, to actually obtain the very pure nanoparticles.

The lack of convenient purification assessment methods is currently a significant barrier to producing highly pure nanomaterials. Finally materials characterization, is another avenue that has come up in the document and throughout the talks. We need characterization tools and methods for each class of nanoparticles that are being produced because we need to really understand the composition and the properties of the nanomaterials.

And as for production or applied research purposes, being able to control the quality control over batch-to-batch variations in production, it would be nice to actually have in situ methods to monitor these syntheses while they're being developed for production purposes.

Here is a summary slide that reemphasizes that nanomaterial synthesis [is designed] to control the properties of the core particle, test biological properties and redesign as necessary. As we understand and define the nanoparticles, we can control the

physico-chemical properties and the hazards in this way so that we actually have nanoparticles with widely tunable properties, and that is a key to enhance their performance and their safety at the same time.

Just a summary slide of proactive approaches to prioritizations of the methods that we feel are needed, methods to develop the purification process, methods to functionalize nanoparticles so that they're tunable, assays for purification, and methods to characterize the nanoparticles and assess the purity, assays to test biological and environmental impact. Most importantly, I don't think that I've actually conveyed accurately to this point is that we feel that this design scheme needs to be done simultaneously to incorporate the biological and toxicity testing while we're developing the nanoparticles.

And so basically what we need to do is we need to learn how to design nanomaterials that have the properties we want and that are also designed from the very beginning to be safe regarding health and the environment.

And if you have anymore questions, here is some contact information. This is me [assistant director, SSNI]. Jim Hutchinson is the director [of

SSNI}. He's a chemistry professor at University of Oregon and Skip Rung is the president and executive director of ONAMI.

Thanks.

(Applause.)

DR. ALDERSON: Any questions? Rick.

DR. CANADY: Hi. Rick Canady.

Thanks. A very interesting presentation.

I have a very basic question and then a secondary question with regard to sharing data. The very basic question is I'm not sure I understand what your organization is. What's your business model? I mean you have to have prospects in order to sort of follow through the process that you're talking about.

DR. MADDUX: We're a brand new initiative that is one of the four major research thrusts of ONAMI. ONAMI is a nonprofit organization that was developed by the State of Oregon to spur economic growth in nanotechnology to bring it into the state and to do it --

DR. CANADY: So you have prospects. You have, you know, products, nanomaterial products that are already being considered for the marketplace that you're trying to tune and you're trying to understand green production processes for?

DR. MADDUX: We're somewhere -- yes, I didn't have enough time to really delve into this. So we have three -- so our initiative is funded actually through government funding at the moment.

DR. CANADY: Okay.

DR. MADDUX: And we have three basic research groups. One is we have a group of chemists and biologists who are trying to develop nanoparticles with widely attainable properties. Our basic nanoparticle that we're working with are gold nanoparticles. Being able to functionalize them using a variety of different functional groups, control the size and shape of them; toxicologists within that group to measure the biological toxicity of those nanoparticles; and then we've also got a group of engineers that we're working with to develop micro reactors to scale up the production of these nanoparticles that are then used by another group of people within our organization that will hopefully be commercially available for making nanodevices and nanostructures.

DR. CANADY: And the second question is actually my third or fourth at this point, but the second question is the data that you're developing, is that going to be available to other entities in some

way?

DR. MADDUX: Yes. It's a database that Robert Tanguay is in the process of setting up, and it's going to be integrated throughout so that other databases will be connected to it, will be easily accessible, that anyone can access for any purpose.

Did I say that right? Okay.

DR. ALDERSON: Other questions? Celia.

DR. MERZBACHER: I'll follow up on Rick's question and ask when because that was one of my two questions for you. I'll ask the other one in a moment.

So it's going to be publicly available. Do you have an idea when that might be?

DR. MADDUX: We're in the processes now of laying the groundwork for that, trying to develop the aspects of the database. That's all. The planning stage is currently available, and there's --

DR. MERZBACHER: I'll talk more off line perhaps. That will be great.

DR. MADDUX: Yes.

DR. MERZBACHER: My other question was you made mention of assay tests that you were developing for doing some toxicity type work. Are you familiar with or in collaboration in any way with the

Nanotechnology Characterization Lab that's run by the National Cancer Institute in conjunction with NIST and FDA?

DR. MADDUX: It's one of our goals. They have contacted us and we've contacted them, and we are hoping to set up initial meetings with them because we would be very interested in working with them.

DR. MERZBACHER: Okay.

DR. MADDUX: Very interested.

DR. MERZBACHER: Good.

DR. ALDERSON: Other questions from anyone?

DR. POSTER: Yes, I had a similar question to the database that was brought up, and I guess you mentioned that you're developing sort of libraries of nanoparticles, and I just wanted to know perhaps maybe if you're making use of the NIOSH nanoparticle library that is currently available on line and could be a good starting point.

DR. MADDUX: It would be a good starting point, but you mean for the toxicity testing or for the synthesis?

DR. POSTER: Yes. It's an area where maybe --

DR. MURASHOV: The NIOSH nanoparticles lab

rate, it shows images of nanoparticles as well as their physical, chemical, and hazard properties. It doesn't really list the toxicological testing, not so much. Just the properties.

DR. MADDUX: I didn't hear. I'm sorry.

DR. CANADY: The NIOSH database, it's NIL I guess is the acronym for it. It has got information about physical-chemical properties about particles. It also has micrographs, electromicrographs.

DR. MADDUX: Of the database.

DR. CANADY: Right.

DR. MADDUX: I thought the question was. "Are we using their nanoparticles?" The database would be integrated. So we would be able to -- the idea is we could integrate all of these other databases with this one. So it would be a uniform database.

DR. ALDERSON: John.

MR. MILLER: Yes. I'm John Miller from the NEHI Working Group.

Since the subject of everything we're talking about today is EHS and you're the first speaker to come from an actual working environment, what would be the priorities of your institute in terms of the EHS issues that affect your laboratories,

your workers, your scientists and your own institute?

DR. MADDUX: Well, our institute, of course, we use the safe manufacturing processes, but we're a university lab. So we're actually looking at, at the moment, microgram quantities. So we get that question actually a lot form industry, but it's the standard safety processes that we would use in an academic lab, glasses and hoods and things like that.

So even though we're making greener nanoparticles, we still are very cautious about safety, the safety issues of our lab. But to give you an example, the chemical reaction that Jim Hutchinson developed in his lab was to make gold nanoparticles. The traditional method involved, benzene and diborane gas, and now they use borane dihydrate and toluene. So it's not as flammable, and it's greener, but it still requires organic reagents. It's greener, but it's not water, you know. So you still have to take safety precautions.

DR. ALDERSON: Other questions?

(No response.)

DR. ALDERSON: Okay. Thank you.

(Applause.)

DR. ALDERSON: Before I announce our other speaker, I forgot that we only had one additional

speaker sign up this morning. So we probably have time for an additional two speakers this afternoon if anybody would still like to sign you. You can see Audrey outside and there's a sign-up sheet out there. So if you want to make a presentation, five minutes, at the end of the day, please let us know.

Our next speaker is Dr. Rama -- I'll try to get this right -- Venkatasubramanian. Is that okay? And he's from RTI International.

Rama.

DR. VENKATASUBRAMANIAN: Okay. Good afternoon, folks. First of all, I want to tank the organizing committee and NCI for taking this initiative of opening up this idea for all to come in and certainly I'm not an expert in this area in terms of the environmental aspects.

So, first of all, I'm speaking on behalf of a fairly reasonable team here from OTI and Duke University. So bear with me if I'm not able to answer all of the questions, but certainly I appreciate the opportunity for coming here and being able to share.

And before I launch into this presentation, I want to follow up on the last comment that the other gentleman had for the previous speaker. Is there a lot of issues of safety in all of this

stuff?

You go back 50 years ago for the semiconductor industry. There was always this concern about you use toxic dopants like arsenic and gallium arsenide, I mean, in silicon, borone, diborene and all of this stuff.

The industry has overcome that, and every major icy chip fabrication lab, I mean, you know, plant or even a university research lab has to have safety procedures. And so I'm being optimistic here that we will overcome most of these safety issues, and we will develop a lot of products.

So with that optimistic note, I want to actually also point out that the concept of these nanotechnology and the safety is not just an issue. It is certainly an issue for nanoparticles because they are mobile and they can go all over the place, but nanotechnology itself is beyond nanoparticles because there are a lot of publications of nanotechnology which is not involving nanoparticles. It's based on ten thumbs (phonetic) control that nanometer scale. For example, just to drill on it for a few minutes, we have created nanoscale thermoelectric materials which are put down as film. I mean, fundamentally there are no safety issues other

than in a standard semiconductor industry process.

So I want to make sure we understand that nanotechnology is beyond nanoparticles, and suddenly we don't want to cloud the whole area, but you know, maybe some of the safety issues should be limited to nanoparticles as such.

The second thing I want to point out is suddenly there are new paradigms that are needed for understanding nanoparticles, and based on some of the presentations we had this morning from Sally as well as -- I forgot the first speaker. So both of them would like to indicate a lot of requirements for setting the nanoparticles.

So the other point I would like to make here is whether you do in vivo or in vitro, make sure it is in nano. Okay? Because very often I have found that people go after studying these nanoparticles and they agglomerate, and then they come up with a whole bunch of things which may not be directly pertaining to the safety because some of these properties and functionalities are directly related to the size and how well isolated these are.

So towards that end I would like to actually propose a concept. We suddenly need a whole bunch of nanoscale probes. I mean even today people

don't know how to control these nanoparticles, you know, individually.

So we need a whole bunch of nano probes, and I'll present here what we call sudden nano calorimetry in this direction. Suddenly I think this is a great area because we are going to control and understand the chemistry of these nanoparticles, and there's going to be a phenomenal amount of science that is going to come out both in physics and chemistry, and I believe in biology as well.

So this is a great area for all of us to be involved in.

Okay. Without spending too much time, I wanted to make sure that we do understand here that nanoparticles can have the functionality without making them move around. For example, there are carbon nanotubes that are tethered to the surface of like a silicon substrate, and they do wonderful things like moving heat. And so carbon nanotubes may not be put together in a group that they can cause harm.

So I want to point that out, that it can be engineered sometimes on a template.

The second thing, some of the freestanding nanoparticles that can get disposed in a quite toxic nature, if you can tether them in some situations,

they may still have the functionality without having the toxicity.

And certainly as we look at these nanoparticles and how they behave, suddenly we have to understand that the surface reactivity and the geometry do all intricately related, and therefore, we should probably think of a better name than nanoparticles or utilize perhaps in a restrained fashion, and still they have maybe by changing the molecular nature we can still get the functionality without causing the toxicity.

With that kind of a little bit of an overarching background, let me see what we're talking about. I mean, that is the value for nanotechnology without worrying about the safety issues. So what I would like to show here is what we have done here in the advanced nano thermoelectrics, where we have been able to create the layered structure using fine nanometer, all nanometer scaled structure to control the properties of photons and electrons and to get a significant jump in what is called the figure of merit.

Without getting into all of the details, there have been, in addition to our work from OTI, there have been other works from MIT, Lincoln Labs,

and Michigan State. Using the concept of nanotechnology and suddenly here are nanostructures.

The reason why I bring this up is there is nanotechnology today addressing fundamental issues in energy and electronic schooling and other things where you don't have to worry about the safety issues. So we want to make sure that the community understands there's nanotechnology beyond nanoparticles.

And certainly using the nanotechnology we have made a significant improvement in what is called the figure of merit in over 40 years, and it has got applications in refrigeration. I mean where you can have a solid state refrigerator compared almost in performance to mechanical refrigeration and very high speed cooling. A more recent article from Intel which points out that using nanotechnology and nanoscaled materials, you can indeed get what is called thermoelectric based cooling, which is comparable to mechanical systems, but at the same time it can be fitted inside the package.

In fact, another point of differentiation I want to make here, that using a nanoscale material we have been able to actually cut down the amount of material here for the same functionality compared to what is commercially available. For example, using a

nanoscale material, we are using one-forty-thousandth of the material for the same functionality. So I see environmental relief if the nanoscaled material, nanotechnology is implemented correctly.

So more relevant for this audience where you are focused on understanding nanoparticles and how do you control the chemistry, how do you understand the chemistry, I want to show a specific example of what this technology can do.

So certainly based on today's presentation by Dianne Poster and Sally Tinkle, there is clearly a need for characterization of nanomaterials, nanoparticles. The biological response to the engineered nanoscaled material, and what is the mechanism of the cellular and the monitor level?

I submit to you that the toxicity and other functional aspects clearly can be understood if you understand the chemistry of the nanoscale. And if you're going to study the chemistry of the nanoscale, you've got to have a nano probe of something that you can understand at the nanoscale, and chemistry as it is, at least a picture is going to be driven by kinetics, and most of the time and can be understood by calorimetry.

Clearly, there is a need for something

like a nanoscaled calorimeter, or I'm sure this is from my perspective. Suddenly there are going to be a host of other nanoprobes that are going to be needed for understanding the chemistry of the nanoscale.

So with that kind of background and the overarching theme, let me give you an example of what a nanocalorimeter can be. It can be in vivo or in vitro by suddenly all the processes, biological processes, for example, have a tumor component. Okay? And this is not me speaking and being an electrical engineer. This is an M.D. from Duke.

So basically he does feel that if you take most of the biological process, and hardly have chemistry at work and you have all of these things like plant and intermetabolism or growth rate. Every stress response, drug and metabolic interactions and everything else ending in apoptosis, everything is thermally controlled.

And, therefore, if you can come up with a nanoprobe, thermal probe, it is, indeed, possible to probe at a cellular level or organic level or even a nanoparticle, for example. You know, what is it doing?

And the idea is actually to use a nanotube, which is tethered to a thermoelectric

device, and [determined] the heat of this reaction at the molecular level and treated as a nanoscaled probe, and convert the temperature differential into voltage, and basically you're all used to thermocouples. We are talking about nanoscaled thermocouples basically. Okay?

And be able to take that specific reaction and metabolic process. I mean, take the enthalpy of the reaction and be able to characterize what's going on at the nanoscale.

And compared to some of the other technologies, fluorescent tags and other approaches, I want to submit here that you have high resolution, high speed. The long term observation is possible. There is basically nondestructive potentially if it means there's an advantage, and in general it does not require development of specific tags or possibility of, you know, optically changing the chemistry.

And without getting into the specifics, let me give you the working arrangement. So basically you can use a thermoelectric device like here -- you have shown -- and you can attach these carbon nanotubes. These are sensitive probes and they are firmly attached so that they don't get disbursed. At the same time they can one dimensionally conduct the

heat of the reaction to this cooler, and thereby you can understand the chemistry of this nanoscale reaction.

This is the last slide. Let me go to the last slide here to give you a feel for what this probe is capable of at least on paper.

Okay. If you go to the back of the envelope calculations, you can actually estimate that the combination of a very fine thermoelectric device and a carbon nanotube that can probe the entire heat and deliver it to this device, it is possible to detect heat levels of an autocalorie. So this is perfect for studying the reaction chemistry of the nanoscale, and I believe you need techniques like this if you're going to understand the chemistry and the biological implications of all of these nanoparticles.

And I think I'll stop there and be able to answer any questions that you have.

Thank you.

(Applause.)

DR. ALDERSON: Any questions? Sally.

DR. TINKLE: So would you argue that there are more devices, more development and instrumentation coming along fairly rapidly since this is your area of expertise? How do you see that developing to answer

some of the research needs that have been discussed so far today?

DR. VENKATASUBRAMANIAN: Yes. For example, for any research and development you need to have a need for it, right? So my point here is that if you're going to understand these nanoparticles, their impact or the molecular level impact, you need to be able to understand the chemistry at those kinds of levels.

And there are tools potentially that can be designed to study these things. So I wouldn't say they're available today, but certainly they are within the realm of development.

DR. TINKLE: And I may have misunderstood. I thought earlier you made the point when you were discussing mobile versus restrained materials, those that were tethered or immobilized, that there were not EHS issues associated with the tethered and immobilized materials?

DR. VENKATASUBRAMANIAN: What I wanted to point out here, a lot of these -- let's take the example that Andy had, right? I mean, he had this freestanding particles. If the manufacturer, for example, had actually made a colloidal suspension and delivered a liquid product, okay, 99 percent of the

particles, I mean, the inhalation of getting it on the skin and all of those things would disappear. Then you would worry about what does it do to your internal organs or, you know, if you have some residue of things that you dump in the drain, then that's it.

So most of the functionality, if it can be retained and keep the particle tethered, a lot of the toxicity issues could disappear. That's what I was trying to make.

And one of the ways to tether these nanoparticles -- I mean, people have done this with carbon nanotubes -- is to actually grow these nanotubes on a sort of free standing, grow on a substrate so that they are anchored. Okay? So for a lot of the applications of carbon nanotube they are perfectly fine. So what I was submitting was people should look at the functionalities of nanoparticles that kind of different in a substrate on a template fashion.

DR. TINKLE: And you have measured that in your laboratory to know that tethered materials have fewer EHS implications than non-tethered materials?

DR. VENKATASUBRAMANIAN: No, no.

DR. TINKLE: That's conjecture.

DR. VENKATASUBRAMANIAN: Yes.

DR. TINKLE: Thank you.

DR. ALDERSON: Other questions?

(No response.)

(Applause.)

DR. ALDERSON: We have reached time for a break. So plan to be back by three o'clock. We'll start promptly then.

(Whereupon, the foregoing matter went off the record at 2:39 p.m. and went back on the record at 3:01 p.m.)

DR. ALDERSON: Our first speaker for the remaining session is Sean Murdock from the Nano Business Alliance.

Sean.

MR. MURDOCK: Thank you very much.

Can I kick off the last session, which I suppose is only slightly more fun than being the last speaker of the day, David Berube. Let's get going here.

Real quickly, just some context for those of you who don't know about the NanoBusiness Alliance. The NanoBusiness Alliance members consist of those involved with commercializing nanotechnology. Membership ranges from small research phased start-ups that are working to translate fundamental discoveries

on university campuses to most of the pure play nanomaterial manufacturers to Fortune 500 companies.

And the thing I want to emphasize is that member companies are really truly strongly committed to the responsibility of development of nanotechnology. People understand that safe development is going to lead to good long term outcomes and ultimately better profitability for the companies at large.

And I've been surprised and enthused at the extent to which member companies have shown a willingness to engage with NIOSH, with the EPA, and the voluntary stewardship program and participate in the peer consultation sessions. I'll come back to that a little bit more.

This is going to teach me to do eye charts because I can barely read what I have down there.

You know, before we dive in, you know, I do want to say that the statement was made earlier that prioritizing nanotechnology research is not rocket science. Having said that, as somebody that leads an organization with a diverse constituency, I understand the challenge of coordinating multiple entities and getting information and digesting, synthesizing that. It is a Herculean task. So I do

want to recognize the efforts of the NNCO and NEHI in putting this document together and establishing this first step.

I also want to point out that, you know, efforts like this, while some may say are delayed and not taking place as early as we would like, are unique and really have the potential of pulling us down a more proactive pathway for the development of nanotechnology and is in contrast, you know, to the waves of materials innovation in the past that people referred to as having made some mistakes in the steps.

The one question before I dive into the document and prioritizations and some of the other questions is a question of scope and context. I know there was a decision to exclude naturally occurring nanomaterials and incidentally produced nanomaterials, you know, from this document and from the research needs perspective. I just postulate that it could eliminate an important source of context, and ultimately learnings that may be counter productive.

The embedded assumption is that there is qualitatively different behavior between engineered nanoparticles, intentionally engineered nanoparticles and the incidentally or unintentionally engineered nanoparticles and naturally occurring. And I don't

know that that has been established yet.

Second, there is a wide body that is pointed out in the document of research and understanding of particulate matter in that that we do have and often you can generate significant learnings by understanding comparisons and differences between the behaviors, and it may help us to rapidly bound the hazards and risks as we set about this near term prioritization.

And third, of course, we all hope that some of these incidental engineered nanoparticles will play a role in reducing the emissions of the incidentally produced nanoparticles through combustion over the longer term, and I know that is a longer term solution, but it is important to keep it in context.

Overall, we would say that this document is a solid first step with a need for rapid follow-up to finish the strategic plan. The document, I think, accomplishes what it set out to do, which was, you know, first it is the first systematic and structured collection of EHS research undertakings and future research directions within and across the agencies. It provides a baseline if you talk about the adaptive management going forward to know what's out there and to do the gap analysis, and it, along with this form,

again, is bringing all of the stakeholders to an understanding of what is out there and starting to develop a shared vision of what exists and what needs to be done.

You know, having said that, it is not yet a top level strategic plan since it doesn't have critical elements that would be included related to cost, time lines, and priorities that are very much needed to accelerate and coordinate the nanotech EHS research not only within the government but on the international level and with the private sector, which is urgently needed.

I believe that, you know, the principles that you guys have asked for feedback on the principles for prioritization. We believe that, you know, those principles are, in fact, sound. I'll dive a little deeper.

But you know, as we go about this, more detailed understanding of the current situation is required to really employ those principles in doing the prioritization. The first three we have up there is really about the value of the information, the extent to which the information will reduce uncertainty about the risks and benefits, the extent to which the information provides broad knowledge

about classes in nanomaterials, and the potential to leverage existing data, and again, the incidental and naturally occurring may provide good leverage there, but also research related to limiting bioavailability or removing known toxics from processes.

I'm going to emphasize the next couple. The extent of the expected use for the nanomaterial. The exposure potential for workers, consumers, and the environment through the nanomaterial used in or designed for applications, and then a couple that I have added that I think might be worth considering. They are really building and clarifying the previous ones, which is the extent to which the research drives down the cost or increases the capacity to absorb information in the future, and again, this is part of the strategic planning that relates to dynamic considerations as opposed to static considerations.

There is some research that we simply cannot do today for which the metrology and characterization tools are required, and there is some research from the application oriented research that's going on in the molecular diagnostics world and biotech world that will increase our ability to process information and learning going forward that should be considered as well, and critically

understanding the dependencies and interrelationship between the research programs that needs to be mapped out to accomplish that.

And of course, the cost. And it is not to be said that the cost is limiting, but the cost is informing as we figure out what is, in fact, needed to implement this research program.

We would like to point out that, you know, again, members of the ACC CHEM panel and the NanoBusiness Alliance have been working with EPA and engaged in the peer consultation sessions for the voluntary nanomaterial stewardship program, think that it could be a very valuable source of information for these things in terms of the materials, what's actually in commerce, what's coming down the pipeline, the processes and what safeguards are in place, provided that it is, you know, well designed, well constructed and protects the confidential business information so that people engage in the process.

Further, there is an opportunity to look within the other funding that's taking place within the NNI at things like the SBR program, which tends to fund, you know, start-ups doing translational research from the fundamental innovations which will give insight as to what materials may be coming down

the pike and may be brought into commerce.

So there's an opportunity to use that information to start to get ahead of the curve and prioritize the research going forward. It's this that will provide more clarity around what the very near term needs are, medium term and long term needs.

Pardon me. I'm losing my voice so I'm struggling.

We do believe that leveraging international private sector efforts is critical. I know that numbers of the NSET here have been involved with the OECD working party on manufactured nanomaterials. I think that is critically important. You know, business is, in fact, global now and if we're going to be efficient about doing this, it's not something that one country can or should undertake on their own, and we need to get leverage. You know, as a citizen of the United States, I think it's important that we actually help shape and drive that process. To the extent that we do we'll get more leverage from the 75 percent of the research funds that are taking place elsewhere.

And lastly, we also strongly support the idea of leveraging the private sector, and you know, again, I point out that NanoBusiness Alliance members

have engaged in the NIOSH site visits which Vladimir can speak to and have shown a willingness to engage.

I think that there is critical investment that does need to take place in terms of the communication and supporting that bidirectional communication to establish the feedback to do that. They are resource constrained. Some of them are in the audience, but there's a limit to the resource that they have to engage in these kind of things, and it needs to be provided.

Of course, adaptive management should start now with increased funding. The NanoBusiness Alliance has consistently called for increased funding for EHS research as part of our policy tour over the past couple of years. We did sign on with the letter that's been mentioned a few times that's calling for increased funding, and while I point out that that number that has been used is not a precisely accurate number, it is intended to be directionally correct to highlight the need for increase.

I think that this work that you guys have done as you lay in that next layer of detail that looks at prioritizing the research based upon the materials that are in play and are coming down the pike and what can be done today and what can't be done

today and will be in the future with cost estimates allow that will lead to a bottom up analysis that provides a very real foundation for the size of the funding that is necessary.

In summary, the document is a good first step, but it needs to be transformed into a comprehensive strategic plan with those elements that would make it such. The voluntary nanomaterial stewardship program, SBR grants, and other sources of data could provide the quantitative information that will enable you to dimensionalize or quantify the potential value of the information and to use that as a basis for prioritization, and it's relatively clear that while we don't have all of the information given the body of research that is embodied within the document that it's likely that there is an increase in funding that's required and we need to get after what exactly that may be.

Thank you.

(Applause.)

DR. ALDERSON: Questions? Rick.

DR. CANADY: Thanks very much.

One of the early points that you made was to not exclude incidental nanomaterials, and a question that that would raise, if those materials

were included, would be how to prioritize and how to shape the scope, and I wonder if you could comment on that, with regard to the other point that you made that most of the nanomaterials are going to be incidental.

MR. MURDOCK: And candidly, we, as I said in the slide title itself, it is a question of scope versus context, and I'm not suggesting that we should go create a whole lot of new research on incidental nanoparticles per se, but I think it is useful context that we should leverage off of and potentially to the extent of comparative behaviors, right? So not just looking at these new engineered nanomaterials in isolation, but you know, doing work that looks at how they are behaving relative to those incidentally produced, you know, nanoparticles as well.

So they shouldn't be eliminated from the go forward research. I suspect they should be looking for a comparative hazard, you know, comparative transport, fate. All of those wonderful things can be useful, again, I think in bounding the hazard, but it's not to establish a new, you know, research program.

DR. ALDERSON: Sally.

DR. TINKLE: Sean, you used the term

"rapid," and we've heard it repeatedly through the day, and then we've seen time frames of three to eight years, three to five years. Now, granted that the rapid development of a strategic plan means months, but in terms of the research and in terms of people using words like "it's critical that we," what does "rapid" mean? Is the NanoBusiness Alliance comfortable with a three to eight year time frame? How do we deal with the term "rapid" and terms "critical"?

MR. MURDOCK: That's a tough question to answer the question are we comfortable with a three year time frame. It depends on what we're talking about. Candidly, we need to be focusing on the baseline enabling things like standards, terminology, nomenclature, metrology immediately. We can't wait five to eight years for that because that enables the useful development of information downstream from --

DR. TINKLE: I'm thinking more in terms of things that are going to require research, whether it be applied or more basic. What kind of time frame do you anticipate? Because science takes time, and so whenever I hear those words "I feel pressure to produce data" --

MR. MURDOCK: Let me separate the science

and some of the analysis. Part of what I was suggesting is that I think there is a rapid need for analysis to understand the current situation, to use the information on what's out there, potentially the voluntary stewardship program. That's beyond those other things to figure out where the big issues are likely to be and to truly prioritize those. And that should be rapid.

Science will take time, and it's tough for me to answer in a very high level. What I was saying is some of these things simply can't take place today, and so part of what we would like to see as a useful next step is understanding the interdependencies of what can be done today, what can't be done today because that helps you establish the critical path and the time frames.

DR. TINKLE: So if you went back to the NanoBusiness Alliance with the NEHI strategic plan that laid out a time line and research priorities and the NanoBusiness Alliance and the general public and stakeholders understood that there was a plan, are you suggesting that that would relieve some of the anxiety just to know that we were organized and thoughtful?

MR. MURDOCK: No.

DR. TINKLE: Oh, darn.

(Laughter.)

MR. MURDOCK: No. I mean, as I said, I think there's obviously the plan and then there are, you know -- I think Andrew pointed out earlier there are areas where I think a near term investment probably can at least bound the risk and hazard fairly rapidly.

That's different than figuring out exactly what it is. Some of the issue right now is uncertainty, which people say, "I don't know what the limits are," right? And to get from there and to start to reduce that rapidly, and that means in a year to two years, because ultimately this is a dialogue that's taking place in the public, and there are two parts to reality, that which is and that which seems to be, and if we're not providing some certainty with the strategic plan and taking meaningful action in some areas, then it will affect the perception of risk, which is, in fact, real.

DR. ALDERSON: Vladimir.

DR. MURASHOV: Just a question similar to what Sally is asking. Can you maybe comment on what your members see as immediate research needs and also more longer range research needs?

MR. MURDOCK: Yeah. Let's be clear. So

the first thing is folks are very concerned about having, you know, a safe work place. They're very, very committed to that, and obviously you know that because several of them have had you out for site visits to audit and to do measurements around what's going on there, right? And so establishing an understanding of what the work place protocols are, yes, that's front and center. That is the first line of exposure that will happen, and what I will say is, you know, many of them are focusing on, you know, to the extent possible looking to reduce or eliminate exposures altogether.

There's a difference between research phased companies and manufacturing phased companies. As you move to the manufacturing phase, you tend to enclose processes for reasons of yield, throughput, purity, et cetera, which actually helps with minimizing the exposure in the work place, but that kind of information is absolutely critical in the near term.

DR. TEAGUE: There has also been a lot of discussion about what is the role of the federal government and what's the role of industry. If you take, for instance, the work that you just talked about in terms of near term needs of understanding

exposure and measurement and things that go with that, where would you see as -- what would you see as being the roles of the federal government and the roles of industry in that particular area?

MR. MURDOCK: Well, I mean, we have to develop the mechanisms to, you know -- again, some of the work that's taking place to measure exposure, to understand exposure, to characterize exposure. We have to develop the tests and the methods, the screens that can then, in fact, be used. Industry will apply this knowledge as it happens, but there's knowledge development and standards around that that needs to be developed in order for industry to apply it, you know, simply stated.

And you know, I did make the point that for small businesses it is important that that is aggressively communicated and that that resource is there because it is hard for them to pull and digest and synthesize the overwhelming body of the information. So it's important for us to understand what new developments are there, what's interesting and what's useful and proactively communicate that as well.

DR. ALDERSON: Phil.

DR. SAYRE: Sean, I think I missed

something, but you were listing some additional criteria that you felt were important for prioritization, and I think you had mentioned research that brings down cost or increases capacity. Could you give us a little bit more on that?

MR. MURDOCK: Yeah, and that's a little bit, if you will, abstract and theoretical, but if you talk about -- one way to think about the instrumentation investment, right, is it's increasing our capacity to develop useful information in the area of hazard assessment and the other areas, right? That you need that. You need the standards. You need the consistency to be able to get robust, reliable information.

That's not the only area. The gentleman that just talked about the thermal electrics, he was talking about an application that might be used. I would say that a lot of the work that's happening with the development, applications development of molecular diagnostics and, you know, protein signatures, et cetera, is going to be useful for understanding, you know, and observing what's happening.

And so there are investments. Let me take a specific example. Andrew's Nature paper talked about a low cost, distributed ability to measure

nanoparticle exposure, right? If you could do that, that is tremendously powerful in terms of your ability to then process, get information from a broad range of sources and do it in a rapid fashion. That's a manifestation of that idea, but it's thinking about dynamically how you improve. You drive down the cost of doing this on the -- developing this knowledge by a material basis and how you increase the set of knowledge that you bring in over time, just encouraging to think you know multi-year dynamic effects as well.

DR. SAYRE: So it sort of goes to the instrumentation and metrology area, in particular, which was the cross-cut that we identified --

MR. MURDOCK: Yeah.

DR. SAYRE: -- that supports the other hazard and exposure concerns.

MR. MURDOCK: I think that is a clear near term and other application development will have that effect as well.

DR. CANADY: You partially answered this in your response to Phil's question, but could you expand a little bit more about what you mean in terms of cost being a prioritization factor?

MR. MURDOCK: Actually --

DR. CANADY: This is the bullet after the one that Phil made. Low hanging fruit. Are things rather that are inexpensive but that provide a lot of good information in reducing uncertainty, I understand that cost. But if there's a costly item, say, doing chronic bioassays for every nanomaterial that's below, you know, whatever criteria, that's a very expensive thing, but are you saying don't do that because it's expensive?

MR. MURDOCK: No, no, no.

DR. CANADY: Okay.

MR. MURDOCK: And I would not -- thank you for clarifying that. That probably should not have been listed as, you know, a prioritization criteria per se, but it's important to understand. You know, as I said, this is potentially building from the bottom up a needs based, you know, strategic plan with associated costs so that we can set the budgets, insure that the resources are available. We should not have the cost of the program in any way interfere with the safe development of nanomaterials, right, but it's important to understand those costs, to insure that the resources are, in fact, put in place to be able to implement this research program.

DR. ALDERSON: Sally.

DR. TINKLE: You mentioned in your early slide that you represent small nano technology businesses as well as some Fortune 500 companies. Do you see significant differences in prioritization of their research needs based on the size of the company or health and safety is just health and safety?

MR. MURDOCK: I think everyone is very committed to the health and safety, and I think that's been the --

DR. TINKLE: Not committed, but is what they need, the research they need to have done or the support they need to keep their workers safe significantly different.

MR. MURDOCK: I think everyone is looking for guidance, for the development and emergence of the characterization and the standards across the board. I would characterize that as a no regress strategic move. I think everyone is looking for an understanding of what will be safe practices in the work place with certainty, right? And I think that that's the overwhelming kind of emphasis, you know, at this point in time.

So there's probably more alignment now than maybe there will be in the future.

DR. ALDERSON: Any other questions?

(No response.)

DR. ALDERSON: Thank you, John.

(Applause.)

DR. ALDERSON: Our next speaker is Dr. David Berube from the University of South Carolina, ICON Communications Director.

David.

DR. BERUBE: Thank you for having me here.

I'm coming here with a different message. I'm going to talk about 6(e), which no one has got to, and that's the management part of the document which talks about risk communication. I've been teaching risk communication for about two decades now as a graduate seminar, and when you normally look at agendas and science and look where communication appears, it's usually at the bottom of the list. In other words, everyone gets through all of the real business, and then at the end they get to communication, and this is a bit problematic because to extend the metaphor one more time, this isn't rocket science communicating to the public, but it's not finger painting either. It's an incredible challenge, and what we do at South Carolina is we do a lot of outreach, and we discuss issues of science with the public.

Our goal, I think, is to avoid crisis communication. That is a problem I think none of you want to deal with. Unfortunately over the many years I've served as a consultant in that field, and 50 percent of the companies who come to you don't exist more than six months after they hire you on, and the 50 percent that do exist half of their membership in management is gone, right? And so it's definitely not a dynamic we want to aspire towards.

So what I'm going to suggest is we probably want to have a different model. I come from the USC NanoCenter at the University of South Carolina. We have four major thrust areas, one of which is societal of which public outreach is a big component. We interface with the public on multiple levels, and our newest program will be in the environmental area. We have an inhalation lab that's going on line at the end of this month, and we have a large plot of land we purchased on the coast around Georgetown in South Carolina. We own a substantial part of the estuary system which we're preserving, and also using as a lab, and we just published a recent article on multi-wall carbon nanotubes in the estuarine environment, and that's the direction we're heading in.

We're incredibly lucky at South Carolina. We're a budget line in the state budget. The USC Nano Center gets a million dollars every year, and it can use it discretionally.

So if things develop, that's where we head, and it gives us a unique opportunity to do some work.

I wrote this book, and it's very big in Europe and Japan from what I understand. AT least that's what my agent tells me. There's a lot of references in it.

Two chapters are relevant. There's a chapter on trends in commercialization. There's another chapter which is a primer on nanotoxicology, but the reason I want to bring the book up is when I was writing the book, the biggest challenge I had was trying to get evidence of production and commercialization values, and then when I got the information, trying to figure out which of it was hyperbole and which of it was actual, and it was incredibly challenging, and it's a challenge that I think this group has [to face] more than any others.

Mr. Ziegler this morning was talking about ways to get information from businesses. I think this is a big challenge. I'm not sure SBIR is sufficient.

I think if you go back to the ICF document, which I have read cover to cover, you'll find out that there's a proposal in there which suggests we open up the grant system for industrial participation, which is interesting, and that might provide us opportunities or not, but it's definitely some creative ways of thinking about the problem. We'll get it eventually.

I write a lot of articles. I have a new article in NLBJ, which is the Nanotechnology Law and Business Journal, on a liability business regime that was published yesterday; Nano Perceptions, which is a Swiss magazine is publishing the Magic Nano story, which is the disaster Kleinman went through earlier this year. I have a chapter in a Wiley-Interscience book, which I think a lot of people will find entertaining. It's on the rhetoric of stakeholders, and it claims that not all stakeholders are equal, and that we probably need to figure that out as we progress in this area.

And right now for ICON I've developed a media alert page. We're allowing the media to log into the ICON Web page, and what we're going to do is contextualize toxicological events in the nano-world. We are going through alpha testing.

It required me to have full access to Rice's Web page, which took about six months of negotiating, but we're on line now so you'll be hearing more about that in the future.

I'm getting better at this.

I have a lot of grants. I just want to be up front with you folks. I'm part of the CNS node with Arizona State and UCSB. Mostly at South Carolina we work in outreach images and mental modeling. WE just got an NUE which I'm PI on, and we've developed an undergraduate minor in nanosciences, and the cutest thing about this is at the end of this month over 2,000 first year students are going to read three articles on nanoscience and write discursively on it, which is pretty interesting, and we're doing that as a technique to try to see how we can interface with the undergraduates on this subject, one of which will be on toxicology.

And the reason I'm here is we submitted a NIRT application on a subject called intuitive toxicology. I didn't create the term, but it's a good one, and especially since you can call it I-TOX, which is always good, and we had a lot of discussions as we were putting this together, and I think it's relevant to what we're talking about today.

That's good enough.

The reason we moved into this new area of research is we started work at South Carolina with one, three, and four, and we were quite happy that we had done work over the last four years which helped to answer some of these questions.

And now we're moving into the area of who are the experts, questions of whether scientific information is of high enough quality to become part of the policy process itself; trying to discover what the other sources of information might be; and the last question is just trying to decide who should make all of these judgments.

So this is what our toxicology is about. This is what intuitive tox is. It's a quote right out of my book. It says basically that when you talk to laypersons/public, they tend to determine risk a lot different from experts, and this involves a whole bunch of biases they've rigged into the equation, and these biases can exclude things like probabilities and assessments of hazards.

This is an issue because experts tend to rationalize from dosage or exposure, and the research we have is that the public does not, and we can do a heck of a lot of risk assessment and risk management

but without taking this into consideration, we still have to deal with the public as consumers, and that's the big challenge as far as trying to communicate toxicology is concerned to the public.

So we looked at a whole bunch of tensions that might exist, and the first level of tensions we looked at was the whole concept of what the public is. Usually when you research -- we did this as an undergrad probably. So I'm going to introduce you to the public sphere. They said you had to read Habermas, and you're like, "Oh, God, I hope I don't have to," but you did anyway or at least you got the Crib notes.

And it's all about the public sphere as being some concept associated with representative democracy. Contemporary views of the public sphere have changed, and we now use the word "stakeholder" in the public sphere almost interchangeably.

The first thing to consider in the public area are consumers because that's a very contemporary view of the public sphere. The public is less concerned about participating in the political process and more concerned about participating in the political economy, and the political economy is very broad.

And as consumers they become critically important because you can convince yourself nanotechnology is as safe as it could be, but if the public doesn't buy the products, it doesn't do much for the industry.

The second way to look at stakeholders in this first level of tension is the stakeholders as a potential movement, and that could be somewhat problematic as well, and we have a whole bunch of precursor phenomena that occurred over the last few years, which tell us that there are some likelihoods a movement of sorts might appear, and when we're talking about a movement, we're talking about a protest movement or a boycott movement. And the illustrations are about nanostories: the Silver Samsung washing machine issue. They surface, Friends of the Earth getting closely involved with questions on the safety of nanoparticles and there are a whole bunch of other precursors.

So we have to be cognizant that this is happening, and understand that this could have an impact, and it could affect where nano may be heading.

The last element, of course, is the public as taxpayers, right? The stakeholders as taxpayers themselves. Things nano are going to have to be

continually funded at the federal level, and whether the public actually decides they don't want to fund it or legislators decide that they think the public doesn't want to fund it, it could have a potential impact.

There are some wonderful studies we can do, and I teach a graduate course on the rhetoric of science and technology. We study the Office of Technology Assessment and its demise. We study the phenomenon on the Super Collider and its demise. We talk about the temporary stem cell lines and the problems associated there, and it's incredibly interesting to note the value of stakeholders in the decision making process and how they can impact them negatively and actually positively.

When we were putting together the grant proposal, it involved representatives from Rice University on the toxicology end, the University of Wisconsin in the media end, and the University of South Carolina, as well, participating in media and other areas, and University of Minnesota for their participation in the agri-food area.

We also included Paul Slovic and Leonart Sjöberg, and when we did that, we realized that we probably had 50 percent of the citation files that

existed in the risk field, and when this discussion took place, we had this wonderful round of discussions about nano, and they were really fascinating.

And I'm not going to take authorship of any of these, even though I was responsible for part of them.

The first question was we're in a unique period of time. Whether you're going to call it post enlightenment science or post-post enlightenment science, what we're talking about is that science policy is now being affected by belief and value systems, and the best illustration of that is has to be the stem cell debate in the United States and the research lines. We're not making the types of objective decisions we assume would have occurred after the enlightenment up to this point. There's another variable that's entered into the mix.

The second variable that entered into the mix is this whole concept of post normal science, which is the world which opens science up to understanding there's a lot of uncertainty associated with it, that there are many sources of knowledge, some of which may lay across the layperson/public expert divide, and that we want to have lay participation in the process. Now, whether for good or

bad, this is the contemporary trend in America today, and it's something we have to factor in.

The third thing that surfaced at our discussions is we have now third culture intellectuals. Snow wrote the book about two cultures. We had the literate culture and we had the scientific culture. Well, John Brockman suggests we have a brand new third level of culture, and that culture has to deal with the fact that science literature is becoming popularized. In other words, there are science books that are being sold as popular science. And so the public is getting some information about science, oftentimes not very accurate and oftentimes highly truncated.

The fourth variable we started talking about was science literacy, and we came to the conclusion the deficit model failed. You can't really educate the public up to the point where they understand enough science to agree with science. It doesn't work that way. The truth is the reason you guys are in science is because you had the aptitude for science, and you selected to go into science. The reason they're not in science is they didn't have the aptitude for science and selected out of science. You can't just give them more science and expect them

finally to make the transition, and that's the specific conclusion there.

The last one was there are so many metaphorical visions out there in nano and they're very interesting, two of which I thought were worth mentioning. The first is GMOs and we're quite accustomed to it. We don't want nano to go the way of GMOs. The second is really fascinating because it was just recently announced by the United States Department of Agriculture that food from cloned animals is safe, and you know if you had a background in biology, yeah, it sounds safe. It shouldn't be a problem. It's amazing that the public reacted as negatively as it has in the recent polls. This is a really good indicator. We should watch this very, very carefully because if the public decides they don't want cloned animal products and it's an irrational choice, this may also impact the type of things that could have an effect in the nano world.

We had a bunch of second level tensions we looked at. They were fairly straightforward. That experts use risk assessment, hazard versus probability. Lay persons don't. They use a mental model of intuition. They construct their hazards on their own. They don't really concern themselves

overwhelmingly with probability estimations. They just don't, and that is an issue worth mentioning.

Because technical information that is decoded by the public uses a different algorithm than the experts used to encode the information, you can encode the information as accurately as you want, but it's not going to be decoded that way.

Research tends to support the conclusion that the public brings qualitative factors into their determinations. The physical scientists and engineers and policy scientists assume more and better research will calm the public, and that's just not necessarily true. And it's something we have to realize.

This is your traditional risk algorithm, and it ignores intuition and perception. At least the way we used the O instead of the E here because we talk about occurrence as including exposure.

But the truth of the matter is this phenomenon won't go away, which is that low probability, high consequence events matter to the public. That's why they are so concerned about airport accidents or airplane accidents, but not concerned about motor vehicle accidents, and it's something that's just not going to go away in the near future.

That leaves us with all of this stuff to play with. When we study intuitive toxicology, we have to look at all of the old research that was done decades ago, which is like voluntary risks are not as bad as involuntary risks, all of the Sandman lists. You've probably seen them. It's 12 to 20 long depending on whose view you're counting. There's a lot of research that says dread is a serious variable. In other words, when you start talking about carcinogenicity the public is concerned. There's a lot of concern that outrage is a variable. In other words if you're dealing with highly susceptible populations, especially children and the elderly, it has greater significance. There's a lot of issues associated with stigma. If it's associated with an industry which already carries shame and dishonor, it's difficult for them to get beyond that.

There's a whole bunch of biases that the public brings. I'm not going to go through these because this is just six of the 12 or 15, depending on how you look at it, that the public brings in, but they are definitely alarmist oriented.

The third level tensions which we thought you might be interested in are these. On November 11th, on my blog, I posted a primer on risk

communication. If you want to download it, it's probably a good thing to look at. It covers almost all of the research that's been done in the field for the last two decades.

Also, on December 31st, I did a summary of all of the research needs documents, including most of the ones talked about today. One of the highlights in the risk discussion was risk carries negative valence by its nature. The word "risk" does. The word "kiken" in Japanese carries negative valence, and it's the word for "risk."

Communicating risk regardless of valence increases alarm. Just talking about risk increases alarm. There's great stories about high voltage lines and cell phones there.

[In addition,] rumor of false information is as effective as valid information. There's a good study that was done in France about some poisoning that [presumably] took place which didn't take place at all. It was completely rumor, and it was very effective in changing behavior.

Again, there's a whole bunch of different variables. The last category of variables is that all of this is mediated and none of the research in the past can explain these new phenomena. All of the

research that has been done in the past has not included these types of materials, and this is a real issue, especially with celebrity TV at the bottom. This is the YouTube phenomenon.

The demographic of folks using these as primary sources are your children going through high school at this time and [who] will be the consumers and the citizens of the next decade that can really impact nano. And so we really have to start figuring this stuff in.

Implications? Science arguments are open. They have an open texture to it. They're easy to criticize and uncertainty is manipulated politically, and if we make a wrong-headed effort at public outreach it's going to have strong effects, contagion or cascades. All we need to do is release the wrong information at the incorrect time, and we might experience this.

This is supported by a lot of grants. Thank you very much. If I'm going to leave you with one thing, it's this. Risk communication, like chemistry and toxicology, is not for amateurs. Don't just assume that your project is completed and you can put it on the Web and all of a sudden the public is sated. That's not true. It has never been true, and

we have to take this much more seriously if we really want to get the public involved.

Thank you.

(Applause.)

DR. ALDERSON: Questions? Rick.

DR. CANADY: Thanks, David.

You didn't expect a question from me, did you?

So listening through your presentation, it strikes me that you're talking a lot about evolution of culture, evolution of risk models, mental models, and I'm trying to hear -- maybe I can probe you -- what is novel about nanotechnology. What should we carry forward that's distinct about nanotechnology? And if there's nothing, that's fine.

DR. BERUBE: Because I knew it was coming.

DR. CANADY: Oh, you knew it was coming. Okay. Never mind.

MR.BERUBE: Here are three primary variable bundles you would use if you're doing research to deal with nano. I think the first one we talked about a little bit, is that the communication media has changed qualitatively as well as quantitatively, and we have to get a better handle on that. The YouTube phenomenon and the new demographic

that is actually, you know, using these sources of information are the ones we need to be primarily concerned about, and we need to have a better handle on it and we don't.

The second variable bundle is that toxicology will be released. For example, here's something we've already discovered. The public simply does not understand how industry research is kept confidential. They blame it on the regulatory agencies. Even though you can talk about confidential business information until you're blue in the face, it doesn't matter. They don't understand how it is that an industry gets to market a product that they have to buy and you guys in government can't get them to release the information. They just don't get it. And you can explain in detail over and over again. They still don't want to get it, and the reason is technically we make these assessments in the general public using something called an axiology, which is a big mental model, and what happens is there's interference taking place, and the interference is probably a bias that the public is bringing into the mix.

The public wants labeling, and they don't understand what they want on the label, but they know

they want a label, which is not necessarily a very rational decision on their part, but they would feel much happier if there was a label on it, and even if they didn't understand anything that was on the label.

And research will be released because of all of these new sources of information, not just the sources that were internet related, but the New York Academy in Medicine went on and on about this new gray literature issue they're dealing with. In other words, a lot of people are citing material that has not been peer reviewed. Because of the existence of the Web, a lot of rumors are actually making it into public discussion as if it has been validated information. It has not been fact checked and such. And when it has not been, that's the additional area.

The third variable bundle is the industry is dispersed, and the industry is heterogeneous. So there's no single loci for the communication strategy. It would be really easy if there was just one. If it was just the pharmaceutical industry, we could probably put together a pretty basic plan of action, but it's not just them. It's all of these industries who are using nanoscience as part of their production and part of their product line. I think that's the biggest challenge. It's because of the heterogeneity

of the industry itself. So you don't really have a simple loci point to function on.

Like you can't do a lot of basic studies and panels a group in order to figure out what to do.

DR. CANADY: So does that argue for segmentation of the problem in your mind?

DR. BERUBE: It could be.

DR. CANADY: Okay.

DR. BERUBE: It could be. That wouldn't be very cost efficient, right? It is probably better to try to figure out where the commonalities may rest so that we can develop strategies which are usable across some of the industries and then have unique strategies for some of the other industries or for some of the other product lines.

PARTICIPANT: Yes, I actually want to thank you for talking about communications, and I guess I would like to agree with you in your stressing that perception matters, and so when I think about communication, I think a lot about risk and benefit communication, but it's something I don't think we've heard a lot about today because I think we've been focusing on so much more of what I would call risk attenuation.

So I'm thinking about strategies for us

moving forward, about how are we going to communicate about nanoscience and nanotechnology in what we would like to think is a balanced way. And I like to think about when I think about when I used to teach as well. There are risk attenuators and benefit attenuators. So I used to think about these people as the glass is half full or the glass is half empty.

Can you talk a little bit more about as we start putting our pen down on the paper, what should that look like? What's the first steps?

DR. BERUBE: Are you talking about designing the message?

PARTICIPANT: Un-huh.

DR. BERUBE: Well, the first thing, if we're going to prioritize this, the first thing you need to do is decide how much information you want to release because there's no reason to release all of the information, not that you're hiding information, but there's a lot of information the public is not interested in and doesn't really care about.

The second thing you really need to do is figure out which demographic you need to target because anecdotal evidence suggests seven to ten percent of the public actually pays any attention to science policy making. They don't even vote on it,

but they pay attention to it and it's usually because of an epiphany in the family. Someone had cancer. so they have an actual reaction to it.

That demographic is the one you really want to focus on at least initially because that's the one which is most problematic in most of the other categories.

Once all that is done, you need to discuss where the balance is because you want to increase certainty as you reduce uncertainty. It's not part of the same matrix. At least in risk communication, they're separate events.

I mean I can reduce uncertainty without increasing certainty at all. I mean, there's a lot of ways to do it, but you need to figure out how. It's a set-up of priorities to do it.

The observation the ITOX team had, at least when we sat down and put together the grant proposal, was that what we need to do in risk communication related to nanotechnology is a parallel directive which says if we're going to actually engage the public, this needs to be done while we're doing the toxicology research, right? So we're not taken by surprise when all of a sudden there's a release that occurs. It becomes real public, hits the media, and

then we need to go into crisis mode to try to resolve it. And so [engaging the public] just needs to run parallel.

And compared to the research that needs to be done in the scientific field, this is relatively inexpensive. We don't need labs.

PARTICIPANT: Hi, David.

DR. BERUBE: Hey.

PARTICIPANT: In response to one of your last comments, at EPA we put our grant reports on the Web. They're executive summaries, but there is some data involved in those reports. Are you saying that we should not put -- in terms of not throwing data on the Web or not opening it up to public scrutiny, are you saying that we should not put those data on the Web or are you saying we should scrutinize it before it's put on the Web?

DR. BERUBE: Well, there's a reason to do it for disclosure. There's a reason to use high levels of scrutiny to decide what information you want to release to the public. So it has to be within the public's -- the problem with the public turning to scientific information is if they can't get past the first sentence it's over, right? It doesn't really end.

Paul Slovic has great anecdotes. If it has more than four syllables, don't use it. The public does not like chemical names at all. Put "ene" at the end of anything and they get really nervous.

We need to develop a portal for the public to get information related to toxicology, and that takes planning.

PARTICIPANT: That's understandable, and that's reasoned.

DR. BERUBE: Yeah.

PARTICIPANT: We're not the only ones that are going to be communicating about nanotech, and probably we don't have the most sophisticated means of doing so. With some exceptions in government agencies, the government doesn't do a very effective job.

But I think the big player in this is often industry, and you know, the kinds of mechanisms and sophistication that they use those mechanisms for providing information is much more significant than what we in government do.

Can you talk a little bit about the interaction and the government role in providing information, the interaction between the industry means of providing information and the government's

means of providing information?

DR. BERUBE: Having gone through the grant process, my first observation is make some resources available for people in the field of science communication to actually do this type of research

The second is I'm the communication director for ICON, the International Council on Nanotechnology, which a buddy of mine today said it sounds like you herd cats, which is true. It's an incredible challenge because we have industry components. We have a bunch of academics in the toxicology world. We have representatives from a dozen different, you know, federal regulatory agencies, and then we have NGO folks. Now, releasing a press release is an incredible challenge because it comes with their own interests, but there are ways to develop commonalities and build the levels of consensus. There's a whole field in science communication called consensus communication, right? And they've done a lot of interesting research over the years. It has reviewed a lot of different models and a lot of different countries about how they got the public involved, and I think we need to learn from a lot of this research.

I mean the federal government has to use

portals to reach the public that are designed for the public, not designed as public relation tools for a federal agency, which is the biggest complaint you'll get from the public, right, that it's just pretty much their PR tool is their Web presence?

You know, industry is more savvy because industry obviously has larger budgets it can commit to communication. But you know, we've been reasonably successful in a lot of our projects by hiring some really smart undergrads who have been playing on the Internet for eight years, and you know, it's amazing, what they can do, and with a good bunch of focus groups…

We have discovered -- we have the School for Nanotechnology, the Citizens School of Nanotechnology in South Carolina, and we use them, you know, as a very large sample. And we ask them questions. We discuss sensibilities with them. They tell us what they like. They tell us what they don't like. They tell us what they understand and don't understand, and we try to, quote, incorporate that in our models.

And we need more data like that because we don't have enough data specific to nanotechnology to do that.

Thanks.

DR. ALDERSON: Thank you, David.

(Applause.)

DR. ALDERSON: Our next presentation will be by Dr. Jo Anne Shatkin from the Cadmus Group.

DR. SHATKIN: Well, it has been a long day, especially for those of us who arrived here from Boston this morning. So I'm going to try to keep my remarks to you brief this afternoon.

I very much appreciate the opportunity to address this committee. I lead a health risk assessment practice at the Cadmus Group. We work with public and private organizations on issues of emerging contaminants. Those, of course, include nanomaterials.

I'm also a researcher at the George Perkins Marsh Institute at Clark University, one of the first risk centers in academia, about close to 30 years old now, and I'm very pleased to announce that I'm also chairing a new professional group that is focused on emerging nanoscale materials as a specialty group within the Society for Risk Analysis. This was approved within the past month. So we hope to be a professional resource to other organizations that want to address issues of risk of nanoscale materials.

I don't have a lot of comments about the research topics that were proposed. I thought they were very thoughtful and comprehensive. A caveat: that statement encompasses the additions that others have raised already today.

And as we heard from others, there have been several recent releases of research strategies among different organizations, and it's interesting that there seems to be a lot of convergence about the necessary research.

And I do commend this group as well as the others for adopting a risk based approach, and a risk informed approach, and that is what I'm going to talk about today very briefly, just the three points about the role of risk analysis in prioritizing environmental health and safety research.

One is that I think that screening level risk analysis can be used to prioritize risk research. So, by looking at where the gaps are, and you have mentioned the need for a gap analysis, you can prioritize what research is needed in the short term.

I also think there's a need for research into how to do risk analysis for nanomaterials and also there's mention in this document as well as many others about the need to address life cycle issues,

and so I want to make some comments about that.

In terms of prioritizing risk research, I think that a risk-informed approach can help to formulate what the questions are, that you can identify the scope of the analysis early on in the process and address what questions need to be addressed using a screening level risk assessment.

Obviously early on as you're trying to decide what work to do you're not going to endeavor on a multi-million dollar risk analysis, but in taking a screening-level approach and looking across the life cycle, it can help to identify where the key uncertainties are, where your real data gaps are.

So I offer up as an example a framework that we've developed at the Cadmus Group and have found useful to help in identifying gaps and prioritizing research. I won't spend a lot of time on this, but briefly, by looking across the life cycle of a material and asking the questions about problem formulation at each part of the life cycle, asking questions about whether exposure occurs at different parts of the life cycle can help to understand where you might want to conduct toxicology [research], which part of the product life cycle seems to have the greatest potential for exposure.

And then you can use that [analysis] to figure out where the gaps are, what research needs are really needed.

For example, we heard earlier about that one of the research priorities to look, for example, doing surveillance of neighbors of manufacturing plants. In identifying who your receptors are in a risk assessment, you consider them in the context of other receptors in the manufacturing process. You know, is it the raw material that you need to understand and characterize exposure to or is it the product or its final use that you're most concerned about?

This type of framework can help to get out from under the lamp post, which is where we have some data. We need more [data] to be able to interpret that and I believe this could be helpful.

The second point is that in addition to developing the data for risk assessment, there's a need to understand whether there are nano-specific issues around risk assessment. How are the data going to be used? And to be thinking about that while the data are being gathered and not wait until the data are available, to then start figuring out if the data are appropriate for the question that needs to be

asked.

So it's important to align the data, the research, with the analytical frameworks. This is an interdisciplinary task, and as we all know and we've heard several times today research can answer some questions, but it's going to raise others. So it's very important to be thinking about the end use for these data as they're being developed.

Many of the reports that come out now about the toxicology of nanomaterials report unusual or unexpected results, and so it's important to be thinking ahead about how the data are going to be used when you get a different answer than you thought you'd get from your research.

So what kind of risk assessments are intended and for what purpose?

I think it could prove fruitful to look at existing versus new materials, and I think that's something we heard earlier. I concur with Sean Murdock that there is a lot of existing data. We can use that to ask the question of what is nano about doing risk assessment for nanomaterials. Are there new things that we're going to have to do in the risk assessment process in order to accommodate some of the unique characteristics?

And we might be able to do that by looking at materials that we know already, that we have more information about.

Finally, you know, as someone who has been doing risk analysis, there's a toolbox of approaches and ways of managing uncertainty that risk analysts have developed over the years and those could be useful here. So I think it makes sense to pick up this took box and look at what kinds of approaches people have used in the past when we've had data gaps and see if they're applicable, see, you know, if they fit.

One concern that I have is that, you know, those that might traditionally use a hammer would look at the risk problem as a nail and take exactly that approach and just use the available tools. But I think that if we looked more broadly and use that as an opportunity to see what other tools might be available, that that could be fruitful here.

Okay, and then the third point is on taking life cycle approaches to risk assessment and risk management. It's a significant advance, I believe, to consider a product life cycle for nanoscale materials, but it's not completely clear how to do that. That isn't a traditional approach that we

take in risk assessment usually. We look at a material in a particular context, [e.g.,] does it occur in storm water system or as a food additive?

So I think it's a great idea, but I don't think it's completely obvious how we would do that. I think some research needs to be done, and there needs to be some thought into how to adopt a life cycle approach into the risk assessment paradigm.

I organized a session at the Society for Risk Analysis last month in Baltimore and invited speakers from the government, from industry, from academia, and from the legal community to address this issue of what does it really mean to incorporate life cycle thinking.

And it raised some very interesting issues. For example, Michael Davis from EPA presented a comprehensive environmental assessment framework that he's publishing that incorporates life cycle thinking and looking broadly in the problem formulation phase of a risk assessment.

A professor from the University of Michigan described a life cycle framework for nanomaterials. It was very clear from just these two presentations that how you frame the problem really affects the answer you get. Are you asking a question

about, you know, which material is better from the life cycle perspective or are you asking the question about which material poses a greater risk?

And you get a different answer depending on how you frame it, in fact, even in what units you might use. So I think this is a valuable area for research, and I would consider, ask this community to consider some work along those lines.

So in summary, environmental health and safety research can be prioritized using risk informed screening approaches. I presented one. I'm not suggesting that that's the way to do this, but that thinking about how the data fit into risk analysis can help to prioritize them.

Also, there are many tools in the risk analysis toolbox that could inform directions for EHS research, and research is needed on the process for risk analysis, interdisciplinary research, particularly, I think, addressing this question of what is "nano" about risk assessment for nano.

Finally, I think we need to conduct research on how will we address the life cycle of new materials and risk analysis, and how does this fit in risk management?

Thank you.

(Applause.)

DR. ALDERSON: Questions, please. Rick.

DR. CANADY: Jo Anne, were you thinking about the risk informed -- I'm sorry. Your example was to prioritize using risk informed screening approaches. Are you thinking of this in terms of a case study kind of approach for individual products or across a class of products? How are you seeing this being developed?

I think that it's probably best if we could generalize about materials because there's so many that if you tried to look individually at each one, that could be a very consuming process.

So in the screening process, you know, round particles might fall into one category and non-round particles might fall into another, for example.

DR. CANADY: Right. Okay.

DR. SHATKIN: But I guess I didn't go into a lot of the details of the framework that I proposed, but the idea is that it's an adaptive framework. So it could be adapted to either a whole class of chemicals, an individual material or a product versus or an ingredient, which I think that's another question, is how are we going to manage the difference in doing risk [assessment] for one or the other.

DR. ALDERSON: Yes.

DR. TEAGUE: Right. Jo Anne, I'm not -- by any means, just learning a little bit about risk assessment and risk management, but I was intrigued by your idea of research on risk analysis. Could you say a little bit more about that?

DR. SHATKIN: Yes, I was speaking earlier today with a number of folks about the NAS Red Book, the 1983 "this is how we do risk assessment in the federal government," and that has sort of been the paradigm until, you know, in the last decade or so there's been a lot of new work that's been produced on bringing that up to date in terms of our available science and our ability to look at more detail at some of the parameters like how to characterize exposure.

And it's not necessarily specific to nano that we have these new tools, but I do think that when we start to look at nanomaterials, we're going to see some different aspects that we hadn't considered before in a traditional chemical risk assessment paradigm or a food safety paradigm that will come up. I think it's worth asking the questions about whether there are specific aspects of the way that the federal government and others do risk assessment that need to be changed or adapted to work for nanomaterials.

DR. TEAGUE: So you weren't speaking about various statistical models, Monte Carlo versus others and so on, or were you speaking that?

DR. SHATKIN: It might include -- am I suggesting that we don't use Monte Carlo analysis for nanomaterials? No, that's not what I'm suggesting. I'm not sure I understand what you're asking, but there are other models that we use, for example, environmental fate models.

Are those going to be appropriate to use for nanomaterials, or are those going to have to be updated in order to account for new properties that we don't account for now?

DR. ALDERSON: Sally.

DR. TINKLE: As the discussion this afternoon has -- we've discussed several times the concept of risk management driving or informing very seriously the research prioritization and the sequence in which research is done. As a risk analyst, would you see any down side to that philosophy? Would you support it wholeheartedly or would there be things that you would recommend NEHI be cautious about as it moves down that path for prioritization?

DR. SHATKIN: Moves down the path of?

DR. TINKLE: If NEHI engaged in the

discussion of risk management informing the research needs, prioritization and strategic planning, would there be any concerns you would have that you would want us to be careful in using that mechanism or approach?

DR. SHATKIN: None come immediately to mind. The only thing I can think of at the moment is being attentive to considerations of temporal and spatial variability. You know, what's the concern du jour is not necessarily the most important concern. That can arise in risk management. In fact, it historically often has. So that would be my only caution, is to kind of keep a broad perspective on what's going to really be important.

DR. ALDERSON: Phil.

DR. SAYRE: Jo Anne, in terms of the life cycle analysis, it's pretty clear from your presentation that life cycle will better inform us about exposures, but you mentioned some other areas that life cycle analysis might be helpful. Can you just maybe provide a little bit of clarification there, aside form the overlay on risk assessment paradigm?

DR. SHATKIN: Life cycle analysis will inform exposure more so than toxicology perhaps

because just by nature I'm thinking of what is it that we're exposed to by looking across the product and its use.

But I think that it's particularly valuable in the problem formulation phase where you're trying to decide what risk question are we going to answer with these data. If you think about the life cycle up front in the formulation, that's going to be useful.

DR. ALDERSON: Any other questions?

(No response.)

DR. SHATKIN: Thanks.

(Applause.)

DR. ALDERSON: Our last of the pre-registered speakers is Mr. George Kimbrell from the International Center for Technology Assessment.

George.

MR. KIMBRELL: Thank you, Dr. Alderson.

Good afternoon. Thanks for sticking with us to the end of the day here. Everyone is probably pretty tired. I know I am. So I'll try to be as brief as possible.

I want to thank the distinguished panel and the National Nanotechnology Coordination Office for holding the meeting and for the opportunity to

briefly comment here today on the report and on these issues generally.

Again, my name is George Kimbrell. I'm a staff attorney with the International Center for Technology Assessment, CTA. We're based here in Washington, D.C., and we are a nonprofit, bipartisan organization committed to providing the public with full assessments and analyses of the technological impacts on society.

To that end, we explore economic, ethical, social, environmental, and political impacts that result from the applications of technology and technological systems such as those of nanotechnologies.

I myself work on legal policy and regulatory issues. You may know of us from the petition we filed this past year with FDA on human health and environmental risks from nanomaterials and consumer products.

CTA will also be providing some detailed written comments in addition to my prepared remarks today.

First, I want to applaud the effort that went into this report and the research that has been done here otherwise on these very difficult issues.

Unfortunately, I think the report is lacking in several serious respects. First and foremost, an express primary purpose of the report it seems was to identify specific EHS research needs related to understanding and managing potential risks from nanomaterials and thereby informing and guiding research programs.

Yet the document fails to actually prioritize these EHS research needs or to make any sort of cohesive research plan or strategy. At times it reads more like a laundry list, I would say, of needed information and research.

In addition, it points out gaps that seem to cry out to be made urgent research priorities. For example, it notes there is currently no federal program surveillance of nanomaterials released into the environment. Yet this is not made a research priority.

Similarly, the report notes that there are no studies on the effectiveness of personal protective equipment for manufacturing workers. Yet again, this is not a research priority.

It notes that research on nanomaterials' properties effects on skin penetration have, quote, just begun, yet many skin applied personal care

products containing these same nanomaterials are already on the market en mass. Still this is not a research priority.

Finally, the report notes that life cycle impacts of nanomaterials are generally unknown, quote, yet again this is not a priority. There are many other examples throughout the report.

Instead there are copious amounts of "might be's" and possible research approaches. There are no final conclusions or recommendations. In sum, the approach is an inadequate one as a risk research framework.

Risk research prioritization and a corresponding risk research plan or framework is a basic and necessary step in order to protect human health and the environment.

Now to move on to a few specific recommendations. CTA recommends three major areas of exposure EHS research to be of high priority. First, nanomaterial manufacturing, worker and work place health and safety; second, public health and safety with regards to nanomaterial consumer products; and third, environmental impacts from nanomaterials. I'm going to talk a little bit about each.

First, with regard to worker and work

place health and safety risks, exposures are occurring and protection is required. More than two million people work in the development, production, and use of nanomaterials. Studies document hazard potential and the need for immediate protective action. Current federal approaches do not manage risks arising from thousands of new materials developed each year, and a new paradigm is essential for worker and public health protection.

Public health risks can be managed and research can occur in tandem if a protective approach is taken. Research into public and worker exposures is necessary for protective actions and prudent resource allocation.

Protective measures combined with research into their efficacy serve multiple needs. Primary preventive methods, such as avoiding hazardous feedback, processes and generation of hazardous materials and secondary preventive methods, such as keeping hazards away from people on the environment, should be research priorities.

Research should focus on the efficacy of protective strategies, best practices and policies, and identification of ongoing exposures emphasizing the idea of research in tandem with protective

actions. Rather than laboratory tests to study various options, if we have workers already exposed to likely hazards, it makes more sense to provide the best available protective equipment and work place designs to mitigate exposures and study how well they are working.

Research can be guided to some extent by what we learn about the efficacy of current best options.

While agencies conduct meetings and plan research, sufficient knowledge exists to justify protective action. Research can be used as an excuse for inaction. Instead research should be used now to identify and support development of healthy practices and identify the most protective and efficient policy options.

Substantial research should focus on protective strategies that can be implemented in 2007 to insure the health of workers and the public.

Next I will discuss briefly now consumer products. Worker health and safety is connected to public health and safety. Nanomaterial commercialization continues at lightning speed. According to LUX Research's 2006 nanotechnology report, more than 32 billion in nano products were

sold in 2005, double the amount of the previous year.

The Wilson's Center Project on Emerging Nanotechnologies' consumer database, which has been mentioned numerous times today, lists more than 300 self-identified nanoproducts now on U.S. market shelves.

Nowhere are nanomaterials reaching the public faster than in personal care products. They are the Wilson Center database's largest single category. In addition, on May 2006, Friends of the Earth report found 116 cosmetic sunscreens and other personal care products containing nanomaterials commercially available.

These nanomaterials are free, that is, not fixed in the product matrix, used daily and directly on the skin, may be inhaled and are often ingested. Because of this broad and intrusive exposure, these nanomaterials should be a very high research priority in conjunction with regulatory action from responsible agencies. In that I'm alluding to our petition to FDA and those other issues.

More specifically, dermal exposures and skin penetration of these nanomaterials used in personal care products should be a research priority.

Third, environmental impacts must be an

EHS research priority. Nanomaterials represent a new class of manufactured non-biodegradable pollutants with pathways during manufacturing, transport, use, disposal, as well as intentional release of some nanomaterials into the environment, planned intentional release, that is.

One common and now recurring release is consumer products such as nano cosmetics and other nano personal care products that are washed off in the shower or the bath and join waste water household streams.

Existing studies indicate potential serious environmental impacts and point to urgent need for further study. Potential environmental hazards include, and research priorities should be, mobility, the ability to persist, reach places larger particles cannot, move with great speed through aquifers and soils and settle slower than larger particles.

Transportation. Nanoparticles have a large, inactive surface for absorbing smaller contaminants. Due to bonding and mobility, fertilizers or pesticides could hitch a ride over long distances.

Reactivity. Interactions with substances present in the soil could lead to new and possibly

toxic compounds, and durability and bioaccumulation.

Finally, nanomaterial environmental releases create unique management challenges that must be a research priority. New protocols and cost effective technologies for detecting, measuring, monitoring, controlling, and removing nanomaterials are required and must be an immediate research priority.

Unfortunately, the NNI report devotes only four pages to these important environmental impact issues without setting any research priorities. A case study of the urgent necessity of such research and action can be seen with silver nanoparticles which are being used in numerous consumer products for their antimicrobial properties.

Yet these same enhanced properties are harmful to microorganisms and ecosystems. Due to concerns over environmental impacts of silver nanoparticles, in February 2006 several public utilities and their umbrella organization requested EPA regulate certain of these, quote, silver ion consumer products as pesticides under FIFRA. EPA has now said it will act with at least regard to at least one of these products, a washing machine, although it has taken no action as of yet.

Moreover, a universe of products containing or purporting to contain silver nanoparticles exist and are widely available, including food storage, refrigerator linings, shoe lining, air filters, air fresheners, drywall, paint, medical coatings, and a wide range of other products, many of which you can find in the Wilson Center's consumer product database.

A few thoughts in concluding. CTA would point to the recent article in Nature by Dr. Maynard and 13 others explaining nano safety's, quote, grand challenges that must be tackled in the near future, including developing air and water detection and tracking, developing methods to evaluate nanotoxicity, and developing systems for evaluating and models for predicting health and environmental impacts over the product life cycle.

CTA also supports the Wilson Center's 2006 strategic research plan, also mentioned earlier today and urges the committee to consider adopting research priorities and a research plan rooted in this solid underpinning.

Finally, a word about budget that has been brought up numerous times today. I would concur with the assessments made earlier from all different

sectors, which is that the current paucity of the NNI's budget going to EHS is insufficient to cover all of the many complex issues that need to be researched in the near future, and we join those calling for that number to be substantially increased, at least to 100 million annually.

So with that I'll close. Thank you for the opportunity, once again, to comment here today, and more information and my statement is available on our Website, www.icta.org.

(Applause.)

DR. ALDERSON: Vladimir.

DR. MURASHOV: Thank you for your presentation and thank you for highlighting the importance of occupational surveillance, surveillance of public for potential exposures to nanoscaled materials, as well as exposures to the environment.

I'm a little bit confused though. You said that those needs are not mentioned as needs in the NEHI document. You know, at the same time I see needs listed as collect exposure information, establish environmental monitoring activities, understand work place processes and factors that determine exposures to nanomaterials, quantify a nanomaterial exposure to the general population from

consumer products, industrial processes, and products containing nanomaterials, identify population groups exposed to engineered nanoscaled materials, and so on.

Those needs are not what you're talking about?

MR. KIMBRELL: No. Thank you for the clarification. Perhaps I wasn't clear. Yes, all of those issues are certainly mentioned in the report, the document. That wasn't my point. My point was that while they're all mentioned, there's no prioritization. They're just listed like a checklist of things.

And of course, you don't have to take my word for it. You can read the transcripts from the recent House Science Committee hearing on this point, which was very clear I thought.

DR. ALDERSON: Let me make a comment on that point. I think if you ask any of the NEHI members here, we would all agree with you. There is no prioritization in this document. That is the process we are working on now.

So we agree with you. There is no prioritization. But I think what we need from you and I hope you are going to provide it in your written comments is the items we have listed in the document,

have we covered everything, and the process that we've indicated of prioritization, are there other factors we need to consider in the prioritization process?

MR. KIMBRELL: I think the document is very thorough. I will certainly address anything that I think was left out in our comments to the panel.

I would say that as far as steps going forward, I would have to agree that with the House Science Committee's comments that that may be so, that you're working towards those steps, but I think their understanding was that this document would have that prioritization in it, which it doesn't.

And so I don't think that the urgency is there that needs to be particularly with the manufacturing, the consumer products and the environmental exposures already that far ahead, already exposing, you know, the risks there now. So I would highlight that as my main point.

DR. ALDERSON: Sally.

DR. TINKLE: I would just call your attention to sources such as the NIH CRISP database. I know NIOSH grants are also listed there, where there has been initial research projects begun on most of these activities.

Now, I do not in any way tell you that

this is sufficient or that it is fully comprehensive, but although those particular projects may not be listed in full in the research documents, you may want to apprise yourself of that in a little more detail, and I'd be happy to help you with that.

MR. KIMBRELL: Thanks.

DR. ALDERSON: Rick.

DR. CANADY: Yes, Mr. Kimbrell, I want to thank you very much. This is the most detailed advice we've gotten on priorities, I think, today, and I want to commend you. You've provided examples of what you think are the highest priorities, and I think that's very useful.

I wonder though if you could step back a little bit and talk about criteria that led you to the decisions that you made. One statement you made that I wanted a little clarification on was that animal tests are of a lower priority than work place mitigation.

And there's a criteria imbedded in that. Maybe I misquoted you, and I want you to correct that if I have, but there's a criteria imbedded in that that I'd like for you to elaborate on if you could.

MR. KIMBRELL: Well, I think it comes down to the dichotomy that was made earlier by several of

the presenters in the panel, that being the idea of risk research and exploratory research. I think most of the priorities that I spoke about would fall into the former category, that is, risk research to exposures rather than exploring, you know, with the exception being the environmental where we just know absolutely nothing, it seems, or very little compared to the human health side of things.

So to the extent that there's less money than ideal, that's where our recommendation would be that the money is spent, given the priority of manufacturing being the first line of defense, so to speak. I think it was mentioned earlier, the workers' exposure, and then going to consumers. So it wasn't an accident that I structured it that way.

DR. ALDERSON: Other comments?

DR. TEAGUE: Let me just make one comment, if I may. I think when you look at this document, the total number as indicated several times is about 75 specific research needs, which were picked out and placed into the document as research needs.

In some sense, that's, I would say, a first level of prioritization. Certainly the universe of research needs in environmental health and safety I think includes far more than 75. So the fact that we

have picked out this fairly limited number indicates I would say a first level of prioritization.

For the fact that some of the things that you indicated are, indeed, listed as research needs indicate that the researchers involved in this saw that as a reasonably high priority to make it into the document. Now, that's not to say that all of these are going to be addressed. We still need to go through the prioritization process that Norris is talking about.

But it is in some sense a first cut of what is perceived to be really important areas of research need.

MR. KIMBRELL: I wouldn't disagree with that, Dr. Teague. I would just say that the second half of that critique was the lack of a plan going forward, a strategy for how to implement these priorities, once they're established as such. So I would say that those go part and parcel together.

DR. ALDERSON: Okay. Thanks, George.

(Applause.)

DR. ALDERSON: Well, as we indicated this morning, we have the opportunity for some speakers to register today, and we have four of those, and the first of those will be Dr. Jim Willis, who is Director

of the Chemical Control Division, EPA, and also he is chair of the OECD working party on manufactured nanomaterials. I think that's what he's going to talk about.

Thanks, Jim.

DR. WILLIS: Thanks, Norris.

A pleasure to be here, and I was gratified to hear the OECD working party mentioned a couple of times, and so I'd like to describe very briefly what's going on there.

My discussion is going to be mainly process rather than content because this group has only been working for less than a year, and it's focused on process as opposed to content.

To put this sort of back to beginnings, the chemicals committee of the OECD held a special session on nanotechnology back in June of 2005, really to inform delegations on, well, what is nanotechnology. Are there areas where OECD might be usefully involved?

Now, the chemicals committee has tended to focus on purely industrial chemical type work, really with an eye towards burden sharing among the members and harmonization of things, and one of the key things they've harmonized has been the mutual acceptance of

data program where they've agreed to good laboratory practices and a set of roughly 100 test guidelines which allow for the exchange of data among countries.

Well, on the basis of the special session, the chemicals committee agreed to have a workshop in Washington, D.C., in December 2005. They focused on a number of areas, such as definitions, nomenclature, characterization, environmental effects, human health effects, regulatory frameworks, and how to coordinate internationally on nanotech issues, in particular, coordination with ISO, which has come up today, and I'll get into it in just a bit more time.

They also recommended that there's probably more of a standing need for the chemicals committee to work on the environmental health and safety issues and recommended establishing a subsidiary body, which the chemicals committee agreed to only in February of 2006, which makes it not even a year since this group was agreed to, but the council, which is the group of ambassadors to the OECD, the ultimate decision makers, didn't actually approve forming this group until September of 2006.

So bureaucracy winds its own way whether it's here in the United States or over in Paris.

The working party met in October of last

year, 26th and 27th, in London, with the main task of developing a program of work, and I think lots of people came saying it would be great if we only got this program of work developed. Anything else is gravy.

And, indeed, they developed a program of work. They looked at other things, like what can be done to get the working party off to a fast start. How do you organize the work? How to cooperate with ISO, and indeed, there was an agreement that the Secretariat needed to grab a paper that would go to TC-229 as well as the working party for us to all agree on because there are a number of commonalities, not just Work Group 3, but Work Group 1, and so I think we'll be working together more or less like this.

Countries and observers also reported on their activities in the form of a tour de table, just a document that was developed.

So a program of work was agreed, and that just provides the general framework for operations for 2006 through 2008, and that was subsequently approved by the chemicals committee in November of last year.

So we've got our charge. Now, let me get into just a little bit what we agreed to do to get off

to a fast start because, you know, otherwise it's just this rotating series of meetings that travels around the work. Life is great, but nothing actually gets done.

Six separate steering groups were set up to work on particular projects, and these groups are all starting to meet by teleconference already. One is to develop an OECD research and technologies database, and we were struck at the workshop in Washington, D.C., indeed, by an offer from the Wilson Center to look at how to cooperate with the OECD in possibly adopting the Wilson Center database on research and technologies.

So there's a group formed on developing a database for public access on international research related to nanotechnology.

The second group on environmental health and safety research strategies on manufactured nanomaterials. One element of that would be our contribution was the NNI EHS research needs report that's the topic of today's discussion, but other countries have been doing similar things, and these will be integrated in the work of this group.

We'll also look to what are the priorities internationally. So it will be necessary for us to

look at priorities as well and how countries can work together to meet some of these research priorities.

A third group is safety testing of a representative set of manufactured nanomaterials. Four real tasks here. First is what is a manufactured nanomaterial. What are we talking about?

And we agreed we needed a working definition for this group. We also agreed we'd ask ISO if they could provide us some insight, and so Work Group 1 of ISO is actually going to provide us some input in the coming weeks that hopefully we can adopt with minimal change.

Second is what is a representative set. General agreement, it ought to be representative of nanomaterials either in commerce or likely to come into commerce in the near future, but what specifically are we talking about?

Because the next element is, well, what tests to run to determine some of the intrinsic properties that would be useful for member countries. Those two elements, I think, go hand in hand.

And lastly I'd note that BIAC has agreed to do the testing. Now, BIAC is the business association represented at the OECD. So it is broadly representative of the international chemical industry.

The fourth project is manufactured nanomaterials and test guidelines. As I noted, there are about 100 test guidelines already agreed by the OECD. This group will, among other things, go through those and see which ones may or may not be useful. They'll also look at the work of Group 3 to see what sort of test results are we getting from using a variety of different test guidelines.

And this group will work to, among other things, agree on test guidelines that may be useful for nanomaterials that could facilitate the exchange of information among countries.

The last two groups, I think, are roughly similar. The first group is on cooperation on voluntary schemes and regulatory programs, noting that a number of countries do have either voluntary approaches for nanomaterials. The U.K. has announced a program. Australia has a program. The U.S. is working on a program, and so forth. And a number of countries cover nanomaterials, for example, in their new chemicals program or pesticide programs or so forth.

And the last group is cooperation on risk assessments and exposure measurements, noting that a number of countries are actually engaged in trying to

do assessments.

A number of these projects are obviously interrelated. So it's necessary to sort out the timing resources among all of these in an early stage. Projects 2, 3, and 4 are going to have an early joint meeting in March of this year. The next working party meeting is in April, so almost back to back. Clearly, a need to work urgently on the definition and work closely with ISO on that.

The United Kingdom also offered to chair an activity towards how to communicate the work and vision of this group to member countries and to the public at large, and I think this goes a lot to risk communication issues.

The tour de table, I won't give a summary of what countries are doing. Just note that 18 of the OECD member countries replied, as well as BIAC, environmental defense; environmental NGOs are represented, and Thailand, and that is available on the OECD Website and the URL for that is surprisingly www.oecd.org, pretty easy to navigate the site.

Thanks.

(Applause.)

DR. ALDERSON: Since we are a little ahead of schedule, we will take one question. Vladimir.

DR. MURASHOV: Well, that puts a lot of pressure on me.

DR. ALDERSON: Make it good, Vladimir.

DR. MURASHOV: But anyway, you mentioned that one of the groups formed by this new working party will be looking at strategic planning. When do you think they will develop a product? When do you expect they will deliver some kind of strategy?

DR. WILLIS: Sorry. A strategy?

PARTICIPANT: (Speaking from an unmiked location) research strategy.

DR. WILLIS: Ah. I don't know. I think it will take a while to get a good compilation going because the different reports being done in different countries are all in different formats, and so it's going to take some hard work rolling up sleeves and plowing through these.

Now, the chair of that group is a fellow by the name of Rainer Arndt (phonetic), who is a real slave driver. In case people have never met him, he's German, and he will not be deterred from getting what he wants, which is going to be product.

So I think it's probably a year's time for the group to get its feet under itself and get kind of an array of what countries are doing, and then have a

process to look through the gaps and figure out how to deal with it.

Clearly a lot of this is going to get reflected back to national governments in kind of a clarity with which we're informing. "We," I don't mean the U.S. but I mean all countries are informing this group on what they're doing. Because the French report is going to be in French, and that's just an example of it will need translated.

A lot of these things are going to need to be translated logically as well as literally.

(Applause.)

DR. ALDERSON: Our next five minute presenter is Dr. David Berube. We've already heard from David, but he is going to speak on another subject. So welcome, David.

DR. BERUBE: I'm sorry. I just got this last night. Another example of herding cats is what ICON does.

What I'm here to do is discuss for a few moments a set of workshops that ICON is going to be hosting over the next few months, and they're directly associated with nano EHS research deeds because that's exactly what the project is.

I'm waiting for Windows to do its disco.

But the International Council on Nanotechnology -- I hope you have at least heard of us -- is a multi-stakeholder organization. There's a whole set of academics. There's a whole set of people who are involved in corporate and industry. They exist the whole gamut, from large, multi-national corporations all the way through some start-ups, and really have representation also from EHS groups of NGOs.

Hopefully this will work. Yes.

Hi, Andrew. How are you doing? I'm getting to it.

Andrew is used to me. It's opening up.

(Pause in proceedings.)

DR. BERUBE: I think someone else needs to go next.

PARTICIPANT: Do you want to use this one?

DR. BERUBE: No, I need to get this thing that -- why don't you have someone else come up?

DR. ALDERSON: Okay. Our next speaker that registered is Larry Miller from the Citizens Coalition on Nanotechnology. Is he here? Yes, good.

MR. MILLER: This is pretty scary, I hope you know. I've heard quite a few comments since I came here this afternoon about the public and how you

desire to respond to the public and inform the public, and so on. And lo and behold, here I am.

(Laughter.)

MR. MILLER: So go ahead.

I have no questions. I am a citizen. I am not a doctor. I am not a government employee. I am not a government or a corporate head of some team. I'm just a person, and for that reason I was given a chance to join a group of people at the University of Wisconsin in kind of a class, although we didn't get grades. And I like that part very much. It was a group that got together, and we talked to experts in nanotechnology and studied nanotechnology. I got a chance to ask [the experts] questions, and they talked to us to answer our questions, and we interacted, and at the end we wrote a report.

So this is from the report of the Madison Area Citizen Consensus Conference on Nanotechnology. It is typical, I think, of consensus groups that they come up with names like that. When they ask you what you want to be called, you know, and everybody tells you, you feel that you must put everything into the report and so the name gets really long.

But I'm not going to give you all of the recommendations of that group. I picked out a couple

that I would really like to emphasize at this time.

One was the media coverage and information availability. The public needs more in depth information on nanotechnology research and product development. We recommend increased coverage in the popular media, National Geographic or public television, and in conferences on nanotechnology for lay citizens. Local media should inform people about nanotechnology research and development occurring in the community.

We recommend the labeling of products using nanomaterials. Such labels should distinguish between those nanoscaled materials that are naturally occurring and those that are not.

We recommend that a method for informing the public specifically of potentially harmful effects of nanomaterials should be instituted by the government. This could include warning labels similar to tobacco products or some other appropriate precautions to protect consumers.

We recommend a shared access database to exchange information in order to make it easier for scientists to gain from one another's knowledge.

We recommend that publicly funded research institutions widely circulate, including through

popular media, statements of purpose for research for which grants are applied.

We recommend that scientists regularly report on funding of and results of research in a way that is accessible to lay people. These reports should appear free of jargon in mainstream publications, the largest circulating newspaper in a given locale. These reports should include a statement of the potential risk of any products likely to result from the research.

We recommend that the public have access to the results of nanomaterial safety and toxicity tests done by private corporations.

Now, the next one is much shorter than that, but I think you'll find it -- I don't know how you'll find it.

Creation of government bodies. We should not assume that existing health and safety regulations are adequate to cover products made with novel nanomaterials. Therefore, we propose the formulation of a government body, including a wide spectrum of participants, that is responsible for regulation of public and private nanoscale research and development.

Specifically, this body should monitor safety, production, research, applications,

information accessibility, waste byproducts, and potential side effects and risk and should be based on two principles:

One, that researchers and organizations involved in product development must prove the safety of the materials with which they work and the products they develop.

And, two, that research must always be contingent on the assessment of associated risk.

We recommend the formation of an international agency that would consider nanotechnology issues.

I'd like to point out, and I probably don't need to point this out, but I'd like to do it anyway, that you just heard about all of this from the real experts. I think the things I'm giving you here are familiar to you. I want to point out that this was done two years ago by a bunch of people like me, and I am anxiously awaiting some results from this.

Thank you.

(Applause.)

DR. ALDERSON: Our next speaker is Arnold Kuzmack. He indicates he is a private citizen.

So, Arnold.

MR. KUZMACK: Hi. My name is Arnold

Kuzmack. Some of you who know me know that I'm not really a private citizen. I do work for EPA, but I'm speaking purely in my personal capacity here, and nobody in the agency, as far as I know, knows I'm going to be making these comments.

I had not planned to speak, but I am presenting a reaction that kind of developed out of listening to the presentations today.

The document that was produced here, I think, does an excellent job -- I really mean that -- of taking the kind of existing risk assessment and risk management paradigms and fleshing them out from the to nanomaterials and identifying sort of appropriate things that fit into those categories, and certainly. Certainly, were all of that research to be done, we'd be in a much better state than we are now.

However, I do have a concern, which is that there seems to be relatively little that's kind of "outside the box". I would venture to predict that there will be some big surprises in nanotechnology and the environmental transport in and toxicological effects of nanomaterials and so forth and -- things that we will not have at all expected.

And I can cite several examples in other environmental areas that are where there were similar

surprises. For example, we used to think that waste materials applied to the ground would not get into groundwater. We used to -- we were not aware that certain materials can be transported worldwide and in the atmosphere, deposited in water by and accumulated by fish. We didn't realize that certain exposures could cause frank life threatening diseases decades later.

So there's a lot of precedent for there being some real really big surprises. The question is, okay, so how do we -- so what? And I don't have any easy recommendations here. It's always hard to look for something when you don't know what you're looking for, but I think, first of all, kind of the nanotech community needs to have an openness to those sorts of things when they do appear, and. I think there's also another implication. There were a number of people during the today who talked about how the research should be strictly tied to current needs and immediate needs and so forth. I would suggest that the need for having more of it go into the more basic research areas, where you're more likely to find these surprises, than I was given the impression by some of the folks today were arguing for.

Another sort of general comment was: there

seems to be -- and this also reflects the a kind of conventional thinking as it were -- there's much more emphasis (simply in terms of numbers of pages, reflecting the amount of attention being devoted) on human health as an endpoint as opposed to the health of critters and interrelationships in the ecosystem, and I think that's something that I would recommend be reconsidered.

Thank you.

(Applause.)

DR. ALDERSON: Does anyone have any questions? Yes, Rick.

DR. CANADY: Just one. Thanks. I enjoyed that a lot.

In terms of ecological effects or environmental concerns, is there anything in particular you'd point out that was missing or a level of detail maybe that was missing?

MR. KUZMACK: Not so much that as that I feel looking at the amount of air time is an indication of importance, and there being ascribed to an area. There were just sort of two -and -a -half times the number of pages on human health as on ecological health. It may well turn out that there are kinds of population-related things, related to

sort of changes in habitats, things of this sort. It may turn out that certain organisms are particularly sensitive to these materials, perhaps benthic microorganisms, something of this sort.

And obviously if we knew what those were, we could go and look for them. Since we don't, I think we just sort of need to have an openness and level of funding sort of to give us a reasonable chance of finding those things.

DR. ALDERSON: Rick.

DR. CANADY: Yeah, I appreciated your comment about not ignoring the basic research for the unknowns. Do you have any suggestion or any thoughts about how to approach that other than a rough percentage, other than saying 30 percent should go to basic research for things we haven't thought about or things to that nature?

MR. KUZMACK: That's as good as any, I guess. You know, having been a budgeteer for part of my career, there's no magic in it. You just have to go with what your gut says.

DR. ALDERSON: Thank you again.

MR. KUZMACK: Thank you.

DR. ALDERSON: David, you got it working?

DR. BERUBE: Sorry, new computer.

ICON is convening a pair of workshops to build upon the works articulated in the NEHI document we're discussing today, as well as other efforts to develop research agendas. The ultimate goal of this ICON project will be to prioritize research needed to establish science based assessments of potential risk of different classes of nanomaterials, both current and emerging, and to validate the classes of nanomaterials and the principles that relate properties of true predicted risk factors.

And we want to acknowledge the support of two NSET member agencies, the NSF for providing funding for the workshop, and the National Institutes of Health, which will be hosting the first workshop at its facility in Bethesda on January 9th and 10th, 2007.

The ICON project is meant to be a useful resource for policy makers grappling with the complex and evolving issues surrounding identification and prioritization of research needs for nanotechnology environmental health and safety issues.

Prioritization requires an assessment of the current state of knowledge of nanomaterial environmental health and safety, which will be enabled by establishment of classes of materials based on

their physical and chemical properties and the principles for their interactions in the environment and with biological systems

In this context, research needs will be prioritized to determine the validity of nanomaterial classes, their biointeraction principles, and on commercial and research relevance as well as hazard and exposure potential. The goal of the project is to engage stakeholders from multiple countries and various stakeholder groups in distilling information on environmental health and safety of nanomaterials into a format that can direct research efforts towards the most critical issues of the next five to ten years, and to lead to methodologies to identify the classes of nanomaterials yet to be discovered.

Understanding these classes of nanomaterials and their interaction principles should facilitate the development of a more effective standard definitions and management procedures.

Ultimately, the outputs of research done in response to the strategy will inform efforts to manage the risk posed by nanomaterials and feedback into future research needs assessments.

Workshop 1 is going to be correlating material properties with biointeractions. The first

of these two workshops to develop the international nano EHS research needs assessment will take place at Bethesda, campus of the National Institutes of Health. A group of over 60 experts from North America, Europe, Asia an Africa representing academic, governmental, industrial and public research perspectives will work to identify properties of classes of nanomaterials that may be important factors in the materials interactions with biological and environmental systems.

In addition, the participants will identify potential hot spots in the life of the nanomaterials, i.e., situations and processes that may lead to unacceptable exposure and hazard.

Specific attention will be given to materials produced in high volume and are of greatest hazard. The outcome will be a matrix of the material attributes versus behavior and biointeraction.

Workshop 2, research needs and priorities. The second workshop anticipated for spring 2007 in Europe will build upon the matrix produced in Workshop 1 and ultimately produce a science based assessment of potential risk of different classes of nanomaterials, both current and emerging, so that research gaps can be easily identified.

ICON members are committed to identifying and closing knowledge gaps that hinder the development of responsible practices for managing the potential risks of nanomaterials to workers, consumers, and the environment.

Pursuant to that goal, ICON published in August of 2005 the first free database of citations to peer reviewed, scientific publications on nanomaterial EHS and maintains this database as a public service. With over 1,600 references, the nano EHS database is routinely accessed by people from around the world.

In November 2006, ICON published a survey of handling practices in 64 nanotechnology work places on four continents to identify critical information needed for worker safety, environmental protection, and product stewardship.

Thanks.

(Applause.)

DR. ALDERSON: Well, that is the end of our presentations, and I personally want to thank all of you who came.

I have had a number of requests for availability of the PowerPoint slides that were presented today. We will be putting up on the NNCO site the government presentations immediately. Before

we can put up the others, we will have to have written permission from each individual to do that.

So those of you who made presentations, you can expect to be contacted probably tomorrow or the next -- yeah, maybe tomorrow or the first of next week to get permission to do that.

Once we get permission, those will go up on the site as well.

For closing comments today, I would like to ask Dr. Carim, our co-chair of NSET, to provide observations and comments.

DR. CARIM: Thank you very much, Norris.

We'll get to this slide in a moment. As Norris indicated, I'm Altaf Carim with the Department of Energy, and I co-chair the NSET subcommittee along with Celia Merzbacher, and I have the privilege of providing some closing remarks.

It has been a very interesting, very productive day, I think, and don't worry. There are only two slides. So we'll try and wrap this up pretty quickly.

With respect to this one, these are some of the areas. This is essentially the same slide that you saw at the end of each of the presentations of the research areas by the NEHI subcommittee members who --

NEHI working group members, rather, who presented this morning.

And I just wanted to reemphasize that these are areas in which we would really like to get information back from you. I may need to modify the phrasing of these a little bit.

With respect to the first one, really looking at this globally, the question is: are the research areas that you've heard about today and that are identified in the document that we've talked about, the NNI EHS research needs report, are those representative of current needs? Are there other things that we should be thinking of that are important and that really need to be added to that?

What criteria should be considered in setting these research priorities? And here we'd certainly be interested in feedback on the criteria that are identified in the EHS research needs document. We've had some comments back on that, and I thank you for that, but we'd like to hear more on that as well as some other suggestions of criteria that we haven't considered or that haven't been discussed today.

The third bullet here really has to do with which research needs are of the highest

priorities in these five areas of categories. We've had valuable comments on this, but I also want to emphasize that the word "priorities" in some sense is one dimensional, and the more you can flesh that out for us, the more helpful it will be. In terms of whether something is high priority may also depend on the time frame. It may also depend on feasibility and other factors.

And finally, any other additional comments or questions or inputs that you have are certainly welcome.

So if we go to the next slide, you'll see how to provide those. Additional comments associated with this public meeting could be submitted as you see and as we mentioned several times, up until January 31st, and the Web site is provided here.

I would also mention that that's the same Web site on which we'll be posting the government presentations from today, as well as others, as permission is received. This is the meeting Website.

And there will also be a transcript of this meeting that will also be available at the same site.

Going through my list, the final few comments I have I wanted to remind you of the next

steps, some of which are underway already and that we've met to discuss, but which we certainly appreciate input on and wanted to make sure to convey to you that these are efforts that are underway to prioritize the research needs, to evaluate in a more systematic way and a more formal way the current research portfolio, to perform a gap analysis based on that kind of information and to continue coordinating NNI activities and address the remaining research needs that we observe.

So with that, I'd like to bring the meeting to a close, to thank all of our presenters, and to thank the audience as well for sticking with us through this and providing your interest and hopefully your comments in writing if you have not provided them already or if you have, any additional comments you might have.

So I certainly encourage you to do that. So on behalf of the NSET subcommittee and the NEHI Working Group, I do thank you all, and also a special thanks to our intrepid NNCO staff who have set up and supported this event.

Thanks to all of you and have safe journeys home.

(Whereupon, at 5:09 p.m., the public

meeting was concluded.)